

Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Idea Award with Special Focus

Funding Opportunity Number: W81XWH-13-PRCRP-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), July 16, 2013
- **Invitation to Submit an Application:** September 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 22, 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) Peer Reviewed Cancer Research Program (PRCRP) 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 PRCRP was initiated in 2009 to provide support for cancer research of exceptional scientific merit not addressed by the breast cancer, prostate cancer, lung cancer, and ovarian cancer research programs executed and managed by the Office of the Congressionally Directed Medical Research Programs (CDMRP). Appropriations for the PRCRP from FY09 through FY12 totaled \$59.8 million (M). The FY13 appropriation is \$15M.

The goal of the PRCRP is to improve quality of life by decreasing the impact of cancer on service members, their families, and the American public. The PRCRP is charged by Congress with the mission to investigate cancer risks that may be relevant to active service members, their families, and other military beneficiaries.

B. FY13 PRCRP Congressionally Directed Topic Areas

To be considered for funding, applications for the PRCRP Idea Award with Special Focus *must* address at least one of the Topic Areas as directed by Congress. Research applications in the areas of breast, prostate, lung (excluding mesothelioma), or ovarian cancer will *not* be accepted. The FY13 PRCRP Topic Areas are listed below.

- Blood cancers
- Colorectal cancer
- Genetic cancer research
- Kidney cancer
- *Listeria* vaccine for cancer
- Melanoma and other skin cancers
- Mesothelioma
- Neuroblastoma
- Pancreatic cancer
- Pediatric brain tumors

C. FY13 PRCRP Military Relevance Focus Areas

In addition to addressing the required Congressionally Directed Topic Areas in Section I.B. above, applications for the PRCRP Idea Award with Special Focus *must* also address at least one of the FY13 PRCRP Military Relevance Focus Areas. Military relevance in medical research focuses on critical health issues of the military experienced by service members, their families, and other military beneficiaries. To address the cancer health needs of both deployed and non-

deployed personnel, their dependents, retirees, and Veterans, the FY13 PRCRP seeks to support studies that are responsive to the Military Relevance Focus Areas listed below:

- Susceptibility to developing cancers due to exposure to militarily relevant environmental or chemical carcinogens (including transgenerational effects)
- Identification of predictive and prognostic biomarkers of developing cancers due to exposure to militarily relevant environmental or chemical carcinogens
- Molecular mechanisms by which environmental influences associated with military exposures alter gene structure, stability, and expression
- Examination of cancer diagnosis and prognosis effects on the psychosocial well-being of military beneficiaries

D. Award Information

The PRCRP Idea Award with Special Focus mechanism is intended to support innovative, untested, high-risk/potentially high-reward concepts, theories, paradigms, and/or methods in cancer research that are ***directly relevant to service members, their families, and other military beneficiaries***. The proposed research project should include a well-formulated, testable hypothesis based on strong scientific rationale and study design.

The Idea Award with Special Focus is not intended to support a logical progression of an already established research project. ***The proposed research project should be novel and innovative.*** Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. Research that is an incremental advance upon published data is not considered innovative and will not be considered for funding under this award mechanism.

Inclusion of preliminary data is discouraged. The outcome of research supported by this award should be the generation of robust preliminary data that can be used as a foundation for future research projects to understand the mechanisms of initiation, or progression of cancer. ***This award is not intended to support ongoing research in the applicant's laboratory;*** therefore, inclusion of preliminary data other than serendipitous findings or in very small numbers is not consistent with the exploratory nature of this award.

Use of Military and Department of Veterans Affairs (VA) Populations: If applicable, access to target military or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving active duty military, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. Inclusion of military treatment or research facilities is encouraged but not required.

Use of Human Subjects and Human Anatomical Substances: All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record.

Local IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives will require information in addition to that supplied to the IRB. Allow a minimum of 2-3 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

Clinical trials are not allowed. A clinical trial is defined as a prospective accrual of patients 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 subject of that intervention or interaction. The FY13 PRCRP is not offering an award mechanism that will support clinical trials; PIs seeking funding for a clinical trial are encouraged to investigate other funding agencies for support. Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects' data, or human anatomical substances. Definitions of human subject use may be accessed at https://cdmrp.org/Program_Announcements_and_Forms/ and https://cdmrp.org/files/forms/generic/Human_Subject_Research.pdf.

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.

E. 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.

F. Funding

- The maximum period of performance is **2** years.
- The maximum allowable direct costs for the entire period of performance are **\$300,000** 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 **2** 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.

All applicants to this Program Announcement must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for System for Award Management (SAM) and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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 for non-governmental personnel
- Research supplies
- 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

Shall not be requested for:

- Clinical trial costs
- Salary for government personnel

The CDMRP expects to allot approximately \$4.8M of the \$15M FY13 PRCRP appropriation to fund approximately 10 Idea Award with Special Focus 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-PRCRP-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 pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

A change in 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**

FY13 PRCRP Integration Panel (IP) members should not be involved in any pre-application or application. A list of the FY13 PRCRP IP members can be found at <http://cdmrp.army.mil/prcrp/panels/panels13.shtml>. 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**

Pre-Application Narrative Form: The Pre-Application Narrative Form is a PDF fillable form available for download on the Full Announcement page in Grants.gov, or under Program Announcements & Forms on the CDMRP eReceipt system (<https://cdmrp.org/>). The form must be completed and uploaded into eReceipt as a PDF.

Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.

The following information must be provided on the form:

1. Which **required** FY13 PRCRP Topic Area(s) will the proposed research address?
2. Which **required** FY13 PRCRP Military Relevance Focus Area(s) will the proposed research address?
3. How will the proposed research lead to a solution for the Military Relevance Focus Areas(s)? (2,000 character limit, including spaces)
4. How is the proposed research innovative and not an incremental advancement of previous work? (1,000 character limit, including spaces)
5. What are the short- and/or long-term impacts of the research for military health care? (1,000 character limit, including spaces)

Pre-Application Supporting Documentation: Supporting documentation for the pre-application is limited to:

- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal 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 used in the Preproposal Narrative.
- Key Personnel Biographical Sketches (four-page limit per individual).
- **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.

Pre-Application Screening

- **Pre-Application Screening Criteria**
To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the PRCRP, pre-applications will be screened by the PRCRP IP based on the following equal criteria:
 - Whether the pre-application addresses at least one of the FY13 PRCRP Topic Areas.
 - Whether the pre-application addresses at least one of the FY13 Military Relevance Focus Areas that meets the program’s goals.
 - To what degree the pre-application proposes research that will lead to a solution for the relevant Military Relevance Focus Area(s).

- To what degree the pre-application is innovative and is not an incremental advancement of previous work.
- To what degree the short- or long-term outcomes of the research will impact military health care.

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

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is 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 notification 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 through the Grants.gov portal (<http://www.grants.gov/>).

Grants.gov application package components: For the Idea Award with Special Focus, 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 (six-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.

- **Hypothesis:** State concisely the new concept, theory, paradigm, and/or method that addresses an important problem relevant to *at least* one of the FY13 PRCRP Topic Areas *and* FY13 Military Relevance Focus Areas.
- **Rationale:** State concisely the rationale for the proposed research. Inclusion of preliminary data is strongly discouraged.
- **Objectives:** State the specific aims and research strategy of the study.

- **Methods:** Describe the experimental design and methodology in sufficient detail for evaluation. Address potential problem areas and present alternative methods and approaches.
- **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 (two-page limit per letter): 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) (two-page limit per letter): 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.
 - 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.

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

Technical abstracts should be written using the outline below.

- **Background:** State the FY13 PRCRP Topic Area(s) addressed by the proposed research. State the FY13 PRCRP Military Relevant Focus Area(s) to be addressed. Present the ideas and reasoning behind the proposed work.
- **Objective/Hypothesis:** State the objective/hypothesis to be tested. Describe the overall research goals.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design including appropriate controls.
- **Innovation:** Briefly describe how the proposed project is innovative.
- **Military Relevance:** Briefly describe how the proposed research is relevant to service members, their families, and other military beneficiaries. Clearly articulate the project’s potential impact on military beneficiaries in terms of advancing cancer research and/or patient care.

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

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract. Avoid overuse of acronyms and abbreviations, if possible. Describe the proposed research project by including the following elements in plain language.

- State the FY13 PRCRP Topic Area(s) *and* Military Relevance Focus Area(s) addressed by the research project.
- 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? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field.
 - What is the projected time it may take to achieve a clinically relevant outcome?
 - What are the likely contributions of this study to advancing the field of cancer research and/or patient care?
- Summarize how the proposed research will benefit service members, their families, and other military beneficiaries.

- **Attachment 5: Statement of Work (SOW) (two-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: Relevance to Military Statement (one-page limit):** Upload as “MilBen.pdf.”
 - Describe how the proposed project is responsive to at least one of the FY13 PRCRP Topic Areas in a *militarily* relevant manner. Describe how the proposed project is responsive to one of the FY13 PRCRP Military Relevance Focus Areas faced by military beneficiaries in cancer prevention, detection, diagnosis, and treatment.
 - Describe how the project will lead to an original and important contribution to the goal of advancing basic, translational, or clinical cancer research, or on the quality of cancer care for service members, their families or other military beneficiaries.
 - Describe the impact, either short-term or long-term, of the proposed research on the basic health, welfare and/or psychosocial wellness of service members, their families, and other military beneficiaries.
 - Describe how the study design will replicate field conditions, if appropriate. If active duty military, military families, or U.S. Veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population.
 - If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Armed Forces, their family members, and/or the U.S. Veteran population).

- **Attachment 7: Innovation Statement (one-page):** Upload as “Innovation.pdf.” Describe how the proposed research is innovative. For example, state how the research examines a new paradigm, challenges existing paradigms, or looks at existing problems from new perspectives.

- **Attachment 8: Letters Confirming Access to Target Military or VA Patient Population(s) or Human/Animal Anatomical Substances, Databases, if applicable:** Upload as “Access.pdf.”

If applicable, provide a letter(s) of support, signed by the lowest ranking person with approval authority, for studies involving active duty military and/or Veteran populations, military and/or VA-controlled study materials, and military and/or VA databases.

- **Attachment 9: Use of Hazardous Chemical or Biological Agents, if applicable (no page limit):** Upload as “Hazardous.pdf.”

The applicant must submit a plan for acquiring, using, and maintaining hazardous agents if such agents are to be used in the study. The plan must contain all applicable information such as Centers for Disease Control and Prevention (CDC) registration, an approved organizational safety plan to use the agent(s), and letters of collaboration, agreement, or approval from government sites issuing any agent(s). Indicate if agents used are purchased commercially, and if so, confirm

that the amount is under regulated limits. Include a statement addressing this requirement along with accompanying letters of collaboration, approvals, and certifications.

- 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, USAMRMC, based on technical merit, the relevance to the mission of the DHP and PRCRP 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.shtml>.

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

B. Application Review Criteria

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

- **Scientific Merit**

- How the proposed research project addresses an important scientific question relevant to at least one of the FY13 PRCRP Topic Areas *and* at least one Military Relevance Focus Areas.
- Whether the research demonstrates the potential to generate robust preliminary data that can be used as a foundation for future research projects.
- How the rationale, experimental design, and methodology are appropriate to test the hypothesis.
- How well the PI acknowledges potential problems and addresses alternate approaches.

- **Innovation**

- To what extent the research proposes new paradigms or challenges existing paradigms.

- To what extent the proposed research is innovative in one or more of the following ways: concept or question, research methods or technologies, adaptations of methods or technologies or other ways.
- How the proposed research represents more than an incremental advance beyond ongoing research and published data.
- **Military Relevance**
 - To what degree the identified military related environment or hazard is supported by evidence, background information, and cited references.
 - To what degree the application is responsive to at least one of the FY13 PRCRP Military Relevance Focus Areas and will advance the understanding of militarily relevant cancer risk factors for service members, their families, and other military beneficiaries.
 - To what degree the proposed research will impact, either short-term or long-term, of the basic health, welfare and/or psychosocial wellness of service members, their families, and other military beneficiaries.

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

- **Personnel**
 - How the research team's background and expertise are appropriate to accomplish the proposed research.
 - To what degree the levels of effort are appropriate for successful conduct of the proposed research.
- **Environment**
 - The degree to which the scientific environment is appropriate for the proposed research.
 - The degree to which the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - To what degree the quality and extent of institutional support are appropriate.
- **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 DHP and PRCRP, as well as 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 PRCRP, as evidenced by the following:

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Programmatic relevance
- Relative impact and innovation

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

A. Rejection

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

- Pre-Application Narrative Form is missing, not used, or blank.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- 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 pre-application or application:

- A FY13 PRCRP 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 PRCRP IP members can be found at <http://cdmrp.army.mil/prcrp/panels/panels13.shtml>
- 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.
- The application does not address at least one of the FY13 PRCRP Topic Areas *and* Military Relevance Focus Areas.
- The pre-application or application proposes breast, prostate, lung (excluding mesothelioma) or ovarian cancer research.

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 Relevance to Military Statement (MilBen.pdf) as Attachment 6.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.	
	Upload Letters Confirming Access to Target Military or VA Patient Population(s) or Human/Animal Anatomical Substances, Databases (Access.pdf), <i>if applicable</i> , as Attachment 8.	
	Upload Use of Hazardous Chemical or Biological Agents (Hazardous.pdf), <i>if applicable</i> , as Attachment 9.	
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.	