Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Idea Award with Special Focus

Funding Opportunity Number: W81XWH-15-PRCRP-IA

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 1, 2015
- **Invitation to Submit an Application:** July 1, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, August 25, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, August 28, 2015
- **Peer Review:** November 2015
- **Programmatic Review:** February 2016

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 2015 (FY15) Peer Reviewed Cancer Research Program (PRCRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). 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 (excluding mesothelioma), 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 FY14 totaled $99.8 million (M). The FY15 appropriation is $50M.

The goal of the PRCRP is to improve quality of life by decreasing the impact of cancer on active duty 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 duty Service members, their families, and other military beneficiaries.

B. FY15 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 FY15 PRCRP Topic Areas are listed below.

- Colorectal cancer
- Genetic cancer research
- Kidney cancer
- Listeria vaccine for cancer
- Liver cancer ***(New for FY15)***
- Melanoma and other skin cancers
- Mesothelioma
- Myeloproliferative disorders
- Neuroblastoma
- Pancreatic cancer
- Stomach cancer ***(New for FY15)***

C. FY15 PRCRP Military Relevance Focus Areas (*Revised for FY15*)

In addition to addressing at least one of the required Congressionally Directed Topic Areas in Section I.B., applications for the PRCRP Idea Award with Special Focus ***must*** also address at least one of the FY15 PRCRP Military Relevance Focus Areas. Military relevance in medical research focuses on critical health issues of the military experienced by active duty 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 FY15 PRCRP seeks to support studies that are responsive to the Military Relevance Focus Areas listed below:

- Militarily relevant risk factors associated with cancer (e.g., ionizing radiation, chemicals, infectious agents, and environmental carcinogens)
- Gaps in cancer prevention, screening, early detection, diagnosis, treatment, and/or survivorship that may affect the general population but have a particularly profound impact on the health and well-being of military members, Veterans, and their beneficiaries

Applications that address exposures, conditions, or circumstances that are unique to the military, or disproportionately represented in a military beneficiary population, are the highest priority, though any applications that address the above focus areas will be considered.

Investigators are strongly encouraged to collaborate, integrate, and/or align their research projects with Department of Defense (DoD) and/or Department of Veterans Affairs (VA) research laboratories and programs.

D. Award Information

The Idea Award with Special Focus supports innovative, untested, high-risk/potentially high-reward concepts, theories, paradigms, and/or methods in cancer research that are ***relevant to active duty Service members, their families, and other military beneficiaries***. The "Special Focus" of this award mechanism is on the cancers associated with exposures, conditions, or circumstances that are unique to the military, or disproportionately represented in a military beneficiary population. The advancement of knowledge in cancer research, patient care, and/or treatment options in the military health system is critical to active duty Service members, their families, other military beneficiaries, and the American public. Military relevance should be articulated with respect to the overall military health system and the mission of the DHP and the FY15 PRCRP. For more information, please review the following websites: Military Health System (http://www.health.mil), the PRCRP (http://cdmrp.army.mil/prcrp/default.shtml), and PRCRP Report to Congress (http://cdmrp.army.mil/prcrp/reports/reports.shtml).

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 highly creative qualities. The proposed research project should include a well-formulated, testable hypothesis based on strong scientific rationale and study design.

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 amounts is not consistent with the exploratory nature of this award.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers 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 requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional 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 FY15 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. For more information, a Human Subject Resource Document is provided at https://ebrap.org/eBRAP/public/Program.htm.

Use of Military and VA Populations and/or Resources: If the proposed research plan involves access to active duty military and/or VA patient populations or resources, the Principal Investigator (PI) is responsible for establishing such access. If possible, access to target active duty military and/or VA patient population(s)/resource(s) should be confirmed at the time of application submission by inclusion of a letter of support, signed by the lowest ranking person with approval authority, for studies involving active duty military Service members, Veterans, military and/or VA controlled study materials, and military and/or VA databases. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Note that access to a Veteran population for clinical studies may only be obtained by either collaboration with a VA investigator where the VA investigator has a substantial role in the research, or by advertising to the general public.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use

Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." ***Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 5, for additional information.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490: 187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.nc3rs.org.uk/page.asp?id=1357.

The CDMRP intends that information, 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 3, Section L.

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.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, 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 anticipated direct costs budgeted for the entire period of performance will not exceed $**400,000**. Associated indirect costs can be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding $**400,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.

- 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.

Refer to the General Application Instructions, Section II.C.5., 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.5. of the General Application Instructions***.

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

- Salary
- Research supplies
- Clinical research costs
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings

Shall not be requested for:

- Clinical trial costs

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 Section II.A. 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 may be executed through a direct fund transfer (e.g., 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.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The CDMRP expects to allot approximately $10.88M of the $50M FY15 appropriation to fund approximately 17 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 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.

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/). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

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.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-PRCRP-IA in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.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@eBRAP.org or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

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**
    - Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF-424 form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
    - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Key Personnel – Tab 3**
    - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
    - FY15 PRCRP Integration Panel (IP) members should not be involved in any pre-application or application. 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@eBRAP.org or 301-682-5507.
- **Conflicts of Interest (COIs) – Tab 4**
    - List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).
- **Pre-Application Files – Tab 5**

  Note: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

Preproposal Narrative: Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

Provide responses in the appropriate data fields for the following in eBRAP:

Failure to complete all data fields will result in administrative withdrawal of the pre-application.

1. State the project's objectives, rationale, specific aims. Describe the methodology and experimental design. (2,000 character limit, including spaces)
2. How will the proposed research lead to promising outcomes for one or more of the selected FY15 PRCRP Military Relevance Focus Areas(s)? (2,000 character limit, including spaces)
3. How is the proposed research innovative and not an incremental advancement of previous work? (1,000 character limit, including spaces)
4. What are the anticipated short- and/or long-term outcomes and how will they impact military health care? (1,000 character limit, including spaces)

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application ***must be uploaded as individual documents*** and are 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 (five-page limit per individual).

- **Submit Pre-Application – Tab 6**
  - This tab must be completed for the pre-application to be accepted and processed.

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 based on the following equal criteria:

  - Whether the proposed project addresses at least one of the FY15 PRCRP Topic Areas.
  - Whether the proposed project addresses at least one of the FY15 PRCRP Military Relevance Focus Areas.
  - How well the rationale and specific aims support the project's objectives. Whether the proposed methodology and experimental design support the project's goals.

- To what degree the proposed project is relevant to the selected FY15 PRCRP Military Relevance Focus Area(s) in a way that is consistent with the program's goals.
- To what extent the proposed research may lead to promising outcomes to address one or more of the selected FY15 Military Relevance Focus Area(s).
- Whether the proposed research is innovative and is not an incremental advancement of previous work.
- To what degree the anticipated short- and/or long-term outcomes of the proposed 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. Full Application Submission Content

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

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

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

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to the application submission deadline***.

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**

   Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the

General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (eight-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 may result in administrative withdrawal of the application.

  Describe the proposed project in detail using the outline below. ***Inclusion of preliminary data is discouraged.***

  - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached in an important problem relevant to at least one of the FY15 PRCRP Topic Areas ***and*** at least one of the FY15 Military Relevance Focus Areas.
  - **Rationale:** State concisely the rationale for the proposed research.
  - **Specific Aims:** State the specific aims of the study.
  - **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation. Address potential problem areas and present alternative methods and approaches. Describe the statistical plan that is appropriate for the experimental methodology being used, if applicable. Include a power analysis for the proposed study. Demonstrate the availability of tissue, data, or human subjects, if applicable.

- **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 will result in the removal of those items or may result in 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: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may 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 support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- 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.
- Intellectual Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - 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 3, Section L 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."** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below.

- **Background:** State the FY15 PRCRP Topic Area(s) addressed by the proposed research. State the FY15 PRCRP Military Relevance 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 and methodology.
- **Innovation:** Briefly describe how the proposed project is innovative.
- **Military Relevance:** Briefly describe how the proposed research is relevant to active duty Service members, their families, and other military beneficiaries. Clearly articulate the project's relevance and potential impact on advancing cancer research and/or patient care for the military health system.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  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 FY15 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?
  - Describe how the proposed research is relevant to active duty Service members, their families, and other military beneficiaries.

- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf."** The suggested SOW format and examples specific to different types

of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the Idea Award with Special Focus mechanism, use the SOW format example titled "SOW (Statement of Work) Generic Format." The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

- **Attachment 6: Relevance to Military Beneficiaries Statement (one-page limit):** Upload as "MilBen.pdf."
    - State the FY15 PRCRP Military Relevance Focus Area(s) to be addressed in the study and articulate how the proposed research will advance the knowledge and understanding of cancer, patient care, and/or treatment options in the military health system.
    - Describe how the proposed project is responsive to the "Special Focus" of the award mechanism on the cancers associated with exposures, conditions, or circumstances that are unique to the military or disproportionately represented within the military beneficiary population.
    - Describe the anticipated short- and/or long-term outcomes of the proposed research and their potential impact on the basic health, welfare, and/or psychosocial wellness of active duty 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 limit):** 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 Resource(s) (e.g., Human/Animal Anatomical Substances, Databases), *if applicable* (one-page limit per letter):** Upload as "Access.pdf."

  If the proposed research plan involves access to active duty military and/or VA patient population(s) or resource(s), include a letter of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

- **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 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 to be 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.

- **Attachment 10: Collaborating DoD Military Facility Budget Form(s), *if applicable:* Upload as "MFBudget.pdf."** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP "Funding Opportunities & Forms" web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.

   - PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf." The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used.
   - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
   - Key Personnel Biographical Sketches (five-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.5., for detailed information.

   - Budget Justification (no page limit): Upload as "BudgetJustification.pdf." The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

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 the SAM with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration 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 DHA RDA Directorate and the Office of the Assistant

Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and PRCRP, 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.shtml.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a nondisclosure 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:

   - **Military Relevance**
     - To what extent the proposed research addresses critical gaps in understanding cancers associated with exposures, conditions, or circumstances that are unique to the military or disproportionately represented within the military beneficiary population.
     - To what degree the proposed research is responsive to at least one of the FY15 PRCRP Military Relevance Focus Areas, fills a knowledge gap, and will potentially advance cancer patient care in the military health system.
     - To what degree the anticipated short- and/or long-term outcomes of the proposed research will impact the basic health, welfare, and/or psychosocial wellness of service members, their families, and other military beneficiaries.
     - To what degree the identified military-related environment or hazard is supported by evidence, background information, and cited references, if applicable.

   - **Scientific Merit**
     - How well the proposed research addresses an important scientific question relevant to at least one of the FY15 PRCRP Topic Areas.
     - To what degree the proposed research demonstrates the potential to generate robust preliminary data that can be used as a foundation for future research projects.

- How well the rationale, experimental design, and methodology are appropriate to test the hypothesis.
- If applicable, to what extent the human subject population is described as being appropriate for the study and there is clear access to the designated population.
- If applicable, to what degree the statistical plan is appropriate for the experimental methodology being used.
- If applicable, whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed.
- If applicable, whether the proposed research using animals meets the guidelines for appropriateness and robustness of experimental design.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- Whether the applicant demonstrates the availability of tissue, data, or human subjects, if applicable.

- **Innovation**
  - To what degree the research proposes new paradigms, challenges, existing paradigms, or is otherwise highly creative in one or more of the following ways: concept or question, research methods or technologies, adaptations of methods or technologies or other ways.
  - To what degree the proposed research represents more than an incremental advance beyond ongoing research and published data.

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

- **Personnel**
  - To what degree the research team's background and expertise are appropriate to accomplish the proposed research.
  - To what degree the levels of effort are appropriate for the successful completion of the proposed research.

- **Environment**
  - To what degree the scientific environment is appropriate for the proposed research.
  - To what degree 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.
  - If applicable, to what degree the intellectual and material property plan is 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 influence the review.

2. **Programmatic Review:** To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, 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 FY15 PRCRP, as evidenced by the following:

   - Adherence to the intent of the award mechanism
   - Program portfolio composition
   - Programmatic relevance
   - Relative military relevance, 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 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 pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

- Preproposal Narrative data fields are incomplete, not used, or left 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.

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.

C. Withdrawal

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

- A FY15 PRCRP 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 documentation. A list of the FY15 PRCRP IP members can be found at http://cdmrp.army.mil/prcrp/panels/panels15.shtml.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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.
- If a clinical trial is proposed, the application will be withdrawn.

- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.
- If the pre-application or application does not address at least one of the FY15 PRCRP Topic Areas, the pre-application or application will be withdrawn.
- If the pre-application or application does not address at least one of the FY15 PRCRP Military Relevance Focus Areas, the pre-application or application will be withdrawn.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.
- If the pre-application or application proposes breast, prostate, lung (excluding mesothelioma) or ovarian cancer research, the pre-application or application will be withdrawn.

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, 2016. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

E. Award Transfers

Refer to the General Application Instructions, Appendix 3, 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

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

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 Grants.gov application package. If the Grants.gov 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	Upload Order	Action	Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Relevance to Military Beneficiaries Statement: Upload as Attachment 6 with file name "MilBen.pdf."	
	7	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	8	Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s) (e.g., Human/Animal Anatomical Substances, Databases), if applicable: Upload as Attachment 8 with file name "Access.pdf."	
	9	Use of Hazardous Chemical or Biological Agents, if applicable: Upload as Attachment 9 with file name "Hazardous.pdf."	
	10	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 10 with file name "MFBudget.pdf," if applicable.	
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.	