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-16-PRCRP-IA

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 8, 2016
- **Invitation to Submit an Application:** July 20, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, September 13, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, September 16, 2016
- **Peer Review:** November 2016
- **Programmatic Review:** February 2017

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 2016 (FY16) 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 (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The PRCRP was initiated in 2009 to provide funding for research of exceptional scientific merit and is managed by the CDMRP. Appropriations for the PRCRP from FY09 through FY15 totaled $149.8 million (M). The FY16 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 and knowledge gaps that may be relevant to active duty Service members, their families, and other military beneficiaries.

B. FY16 PRCRP 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 FY16 PRCRP Topic Areas are listed below.

- Bladder cancer ***(New for FY16)***
- Colorectal cancer
- Immunotherapy* ***(New for FY16)***
- Kidney cancer
- *Listeria* vaccine for cancer
- Liver cancer
- Lymphoma ***(New for FY16)***
- Melanoma and other skin cancers
- Mesothelioma
- Neuroblastoma
- Pancreatic cancer
- Pediatric brain tumors ***(New for FY16)***
- Stomach cancer

*As derived from the National Cancer Institute Dictionary of Cancer terms, immunotherapy is a type of biological therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer. Cancers studied under this topic area should be within the scope of the Congressional language and the intent of the Program Announcement/Funding Opportunity. National Cancer Institute Dictionary of Cancer terms can be accessed at http://www.cancer.gov/publications/dictionaries/cancer-terms.

C. FY16 PRCRP Military Relevance Focus Areas

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 FY16 PRCRP Military Relevance Focus Areas. Military relevance in medical research focuses on critical health issues or gaps in biomedical knowledge that may affect the

health and well-being of the military. To address the cancer health needs of both deployed and non-deployed military personnel, their dependents, retirees, and Veterans, the FY16 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, early detection/diagnosis, prognosis, treatment, and/or survivorship that may affect the general population but have a particularly profound impact on the health and well-being of military Service 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.

For more information, refer to: **Military Relevance Specific to Cancer(s)** (http://www.publichealth.va.gov/exposures/health-concerns.asp). For additional information refer to the PRCRP website: http://cdmrp.army.mil/prcrp/default.

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 highreward concepts, theories, paradigms, and/or methods in cancer research that are ***relevant to Service members, their families, Veterans, and other military beneficiaries***. The "Special Focus" of this award mechanism is on exposures, conditions, or circumstances that are unique to the military, disproportionately represented in a military beneficiary population, or may affect mission readiness. Cancers or circumstances with cancer risk that may affect military families are of special importance to the care and well-being of the military for total mission readiness. 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, Veterans, other military beneficiaries, and the American public. Military relevance should be articulated with respect to the overall military healthcare system, the FY16 PRCRP Military Relevance Focus Areas, and the mission of the DHP and the FY16 PRCRP. For more information, review the following websites: Military Health System (http://www.health.mil), Department of Veterans Affairs (http://www.va.gov/), the PRCRP (http://cdmrp.army.mil/prcrp/default), and PRCRP Report to Congress (http://cdmrp.army.mil/prcrp/reports/reports).

The Idea Award with Special Focus is not intended to support a logical progression of an already established research project. ***The proposed research approach should be 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 not required. 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, the quality of life during and following cancer treatment, etc. ***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) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC 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/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 6, 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 safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. The FY16 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 sources for support. Refer to the General Application Instructions, Appendix 6, 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

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 demonstrating 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, including amendments to ongoing projects. 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 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 6, 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.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf.

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 4, Section K.

E. Eligibility Information

- To be eligible, the PI must have a faculty level appointment (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- Applications with intramural (DoD) investigators named as the PI may be submitted as an "Extramural Submission" through an extramural (non-DoD) organization (e.g., non-profit foundation). 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. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers***. If an investigator at an intramural organization is***

named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- 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**. Indirect costs are to 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.

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 for up to 2 investigators to travel to 2 scientific/technical meetings per year.

Shall not be requested for:

- Clinical trial costs

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Interservice Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions***.

The CDMRP expects to allot approximately $13.44M of the $50M FY16 PRCRP appropriation to fund approximately 21 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(s).

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.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

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.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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-16-PRCRP-IA in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.

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. 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).

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):

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
    - 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 SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
    - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on "*Add Organizations to this Pre-application.*" The organization(s) must either be selected from the eBRAP drop-down 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.

- **Tab 3 – Collaborators and Key Personnel**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - FY16 PRCRP Programmatic Panel members should not be involved in any preapplication or application. For questions related to Programmatic Panel 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.
  - To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest (COIs)**
  - 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). Refer to Appendix 1, Section C, of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

  Note: Upload documents 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: The Preproposal Narrative character limit applies to the text used to describe the project. Non-text elements such as figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc. are not acceptable in the character limit boxes. 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 hypothesis, objectives, rationale, and specific aims. Describe the methodology and experimental design (2,000 character limit, including spaces).
  2. Identify the militarily relevant risk factors associated with the FY16 PRCRP Topic Area(s) in Section I.B. to be studied; ***or*** identify the gap to be studied in the cancer care spectrum (prevention, screening, prognosis, early detection, diagnosis,

treatment, and/or survivorship) that may disproportionately or profoundly affect the basic health, welfare, and/or psychosocial wellness of Service members, their families, Veterans, and other military beneficiaries. Explain how the proposed research will lead to promising outcomes for one or more of the selected FY16 PRCRP Military Relevance Focus Areas(s) in Section I.C. (2,000 character limit, including spaces).

3. Describe the potential short-term and/or long-term outcomes of the proposed research on at least one of the FY16 PRCRP Topic Areas. Explain how the effort is relevant to the healthcare needs of military Service members, Veterans, and/or beneficiaries (1,000 character limit, including spaces).
4. Describe the innovation or how the project may introduce a new paradigm, challenge current paradigms, introduce novel concepts or agents, or exhibit other uniquely creative qualities (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 files*** 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). ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**
  - 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 FY16 PRCRP, pre-applications will be screened based on the following criteria:

  - Whether the proposed project addresses at least one of the FY16 PRCRP Topic Areas in Section I.B.
  - How well the rationale and specific aims support the project's objectives. Whether the proposed methodology and experimental design support the project's goals.
  - Whether of the proposed project addresses at least one of the FY16 PRCRP Military Relevance Focus Areas in Section I.C. To what degree the proposed research may

lead to promising outcomes for one or more of the selected FY16 PRCRP Military Relevance Focus Areas(s).

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

- **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. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

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 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***.

The Grants.gov application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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. **SF424 (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 not required.***

     - **Hypothesis and Objective:** State the hypothesis to be tested and the objective to be reached regarding an important problem relevant to at least one of the FY16 PRCRP Topic Areas in Section I.B., ***and*** at least one of the FY16 Military Relevance Focus Areas in Section I.C.
     - **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, potential pitfalls, and present alternative methods and approaches. If applicable, describe the statistical plan with appropriate power analysis and how it supports the sample size. Research projects may include preclinical studies in animal models, human subjects, and human anatomical substances. If human subjects or human anatomical samples will be used, include a plan for the recruitment of subjects or the acquisition of samples and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects. ***This award may not be used to fund or conduct clinical trials.***

   - **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 Patents: 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.

  If a military/VA investigator is included in the application, letters from the military/VA investigator's immediate supervisor and/or Commander must be provided that demonstrate a commitment to allow the military/VA Investigator to participate in the project.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual Property
  - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    - Clearly identify all such property;

        - Identify the cost to the Federal government for use or license of such property, if applicable; or
        - Provide a statement that no property meeting this definition will be used on this project.
    - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
    - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
  - 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, Section K, 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."** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** 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 FY16 PRCRP Topic Area(s) in Section I.B. addressed by the proposed research. State the FY16 PRCRP Military Relevance Focus Area(s) in Section I.C. 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:** Identify the FY16 PRCRP Military Relevance Focus Area(s) in Section I.C. to be studied. Briefly describe how the proposed research is relevant to active duty Service members, their families, Veterans, 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."** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** 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 FY16 PRCRP Topic Area(s) in Section I.B. *and* Military Relevance Focus Area(s) in Section I.C. 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, Veterans, 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.2., for detailed guidance on creating the SOW.

- **Attachment 6: Relevance to Military Beneficiaries Statement (one-page limit): Upload as "MilBen.pdf."** ***The Relevance to Military Beneficiaries Statement will be evaluated by the FY16 PRCRP Programmatic Panel during programmatic review only.***

  - State the FY16 PRCRP Military Relevance Focus Area(s) in Section I.C. to be addressed in the study.

- Identify the militarily relevant risk factors associated with the FY16 PRCRP Topic Area(s) in Section I.B. to be studied and their short- and long-term impact on the basic health, welfare, and/or psychosocial wellness of Service members, their families, Veterans, and other military beneficiaries.

  or

- Identify the gap to be studied in the cancer care spectrum (prevention, screening, prognosis, early detection, diagnosis, treatment, and/or survivorship) that may affect mission readiness for active duty military or disproportionately or profoundly affect Service members, their families, Veterans, and other military beneficiaries.
- Articulate how the proposed research will advance the knowledge and understanding of cancer, patient care, and/or treatment options in the military health system for the benefit of Service members, their families, Veterans, and other military beneficiaries.
- 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 Service members, their families, Veterans, 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. Describe how the proposed research represents more than an incremental advance beyond ongoing research and published data.

- **Attachment 8: Impact Statement (one-page limit): Upload as "Impact.pdf."** State explicitly how the proposed work addresses a critical problem in at least one of the FY16 PRCRP Topic Areas in Section I.B. Describe the pathway to making an impact on cancer research and/or patient are and explain how the PI's specific research goals, if achieved, would fit into that pathway.

  Attachment 9: 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 10**: **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 11: 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 (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information**.**

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information.

   - 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. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

     Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

   - 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.4., 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.5., for detailed information.

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

   Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.Gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 11, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. 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 or 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.*** 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 submission rejection.

F. Other Submission Requirements

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

All extramural 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 applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and FY16 PRCRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section III.B.2., Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

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

   - **Scientific Merit**
     - How well the proposed research addresses an important scientific question relevant to at least one of the FY16 PRCRP Topic Areas in Section I.B.
     - 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 if 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, addresses potential pitfalls, and 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.
   - **Impact**
     - How well the proposed research addresses a critical problem and/or patient care in at least one of the FY16 PRCRP Topic Areas in Section I.B.
     - To what degree the proposed research goals, if achieved, will contribute to advancing the field of cancer research and/or patient care in at least one of the FY16 PRCRP Topic Areas.

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 **direct** maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement/Funding Opportunity.
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
  - Whether there may be significant overlap with existing or pending awards of the PI or research team.
- **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 criteria are used by programmatic reviewers:

   a. Ratings and evaluations of the peer reviewers

   b. Relevance to the mission of the DHP and FY16 PRCRP, as evidenced by the following:

   - Adherence to the intent of the award mechanism
   - Program portfolio composition
   - Military 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 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.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

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:

- An FY16 PRCRP Programmatic Panel 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 FY16 PRCRP Programmatic Panel members can be found at http://cdmrp.army.mil/prcrp/panels/panels16***.
- 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).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, 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 invited application does not propose the same research project described in the pre-application.
- 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 FY16 PRCRP Topic Areas in Section I.B., the pre-application or application will be withdrawn.
- If the pre-application or application does not address at least one of the FY16 PRCRP Military Relevance Focus Areas in Section I.C., the pre-application or application will be withdrawn.
- 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 organizational investigation. The organization 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, 2017. Refer to the General Application Instructions, Appendix 4, 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 4, for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

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

E. Award Transfers

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program

Announcement/Funding Opportunity version code [20160210g]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

B. 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

C. 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; International 1-606-545-5035

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
SF424 (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	Impact Statement: Upload as Attachment 8 with file name "Impact.pdf."	
	9	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 9 with file name "Access.pdf."	
	10	Use of Hazardous Chemical or Biological Agents, *if applicable:* Upload as Attachment 10 with file name "Hazardous.pdf."	
	11	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 11 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.	