Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Translational Team Science Award

Funding Opportunity Number: W81XWH-16-PRCRP-TTSA

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 Translational Team Science Award ***must*** address at least one of the FY16 PRCRP 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 FY16 PRCRP Translational Team Science Award ***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 these Military Relevance Focus Areas:

- 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 Translational Team Science Award supports *hypothesis-driven* translational studies associated with an ***ongoing or completed*** clinical trial that could lead to a next-phase clinical trial or future clinical application. By leveraging information from ongoing or completed clinical trials, research projects funded by the TTSA should address critical knowledge gaps in outcomes, validate key research and expand upon potential transformative results, or investigate novel findings. Observations from ongoing or completed clinical trials may be utilized to formulate a new hypothesis to move to the next research stage or step of implementation of the clinical outcomes. ***The TTSA is not intended to fund the ongoing clinical trial. Applications associated with a clinical trial not yet started are discouraged.*** The TTSA may support preclinical studies in animal models and human subjects and human anatomical substances. Accordingly, development or use of relevant preclinical models may be included. The TTSA is not intended to support high-throughput screenings, sequencing, etc.

Funding for clinical trials is 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.

If a clinical trial is described in the context of the application package, it is incumbent upon the applicant to ensure that it is clear that the clinical trial associated with the proposed research will not be funded through this award mechanism.

The Translational Team Science Award mechanism requires ***at least*** two, and up to three, Principal Investigators (PIs). One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as a Partnering PI(s). Initiating and Partnering PIs each have different submission requirements, as described in Section II; however, all PIs should contribute significantly to the development of the proposed research project. If recommended for funding, each PI will receive his or her own award.

Applications should include clearly stated plans for interactions among all PIs and organizations involved. The plans must include communication, coordination of research progress and results, and data transfer. Additionally, applications must provide an intellectual property plan to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

Important aspects of the Translational Team Science Award are as follows:

- **Collaboration:** The success of the project depends on the unique skills and contributions of each collaborator. ***At least two, and up to three, PIs must partner in one overarching study in at least one of the required FY16 PRCRP Topic Areas in Section I.B.*** At least one military or VA investigator is encouraged to be included as an equal partner in the research offering both intellectual investment and research effort.
    - A military or VA investigator is an investigator defined as active duty, active reserve, active duty detailed to agencies outside of the DoD, etc., or an investigator at a VA research facility. The military/VA investigator should have a substantial role in the research and should not be included only for access to active duty military and/or VA populations (see 'Military Relevance' below).
- **Translational Aspect:** The application should provide evidence for the reciprocal transfer of information between basic and clinical science or vice-versa in developing and implementing the research plan. Translational research should include correlative studies based on completed or ongoing clinical trials ***(funding for the clinical trial is not allowed)*** or translational research. The application should demonstrate how the study will leverage information from ongoing or completed clinical trials to address knowledge gaps in resulting outcomes, validate key research and expand upon potential transformative results, or investigate novel findings.
- **Military Relevance:** ***The proposed research must address at least one of the FY16 PRCRP Military Relevance Focus Areas in Section I.C.*** The proposed research should be relevant to active duty Service members, their families, Veterans, and other military beneficiaries. Military relevance highlights the need to address exposures, conditions, or circumstances that are unique to the military or disproportionately represented within the military beneficiary population. Critical to the military health

system is the expansion of knowledge in cancer research, patient care, and treatment options. Military relevance should be articulated with respect to the overall military health system, the VA, and the mission of the DHP. 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 the PRCRP Report to Congress (http://cdmrp.army.mil/prcrp/reports/reports).

- **Impact:** The proposed research should have a significant impact on the concepts or methods that are likely to accelerate the movement of promising ideas (in prevention, diagnosis, detection, prognosis, treatment, and survivorship) in at least one of the FY16 PRCRP Topic Areas in Section I.B. into clinical applications.
- **Innovation:** Research deemed innovative may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. Research may be innovative in study concept, research methods or technology, or adaptations of existing methods or technologies.
- **Preliminary Data Required:** Data from an ongoing or completed clinical trial must be included in the application and/or citations of the investigators' work that are relevant to the proposed studies.

Collaborations with a Military/VA investigator are encouraged. All PIs are encouraged to align their research projects with DoD and/or VA research laboratories and programs. While not a complete list, the following websites may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration:

Air Force Research Laboratory
http://www.wpafb.af.mil/afrl

Armed Forces Radiobiology Research Institute
http://www.usuhs.edu/afrri/

Defense Advanced Research Projects Agency
http://www.darpa.mil/

Defense Medical Research and Development Program
http://dmrdp.fhpr.osd.mil/home.aspx

Defense Technical Information Center
http://www.dtic.mil

Military Infectious Disease Research Program
https://midrp.amedd.army.mil

Military Operational Medicine Research Program
https://momrp.amedd.army.mil

Naval Health Research Center
http://www.med.navy.mil/sites/nhrc

Navy and Marine Corps Public Health Center
http://www.nmcphc.med.navy.mil/

Office of Naval Research
http://www.med.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
http://www.acq.osd.mil

Uniformed Services University of the Health Sciences
https://www.usuhs.edu/research

U.S. Army Medical Research Acquisition Activity
https://www.usamraa.army.mil/

U.S. Army Medical Research and Materiel Command
https://mrmc.amedd.army.mil

U.S. Army Research Laboratory
http://www.arl.army.mil

U.S. Naval Research Laboratory
http://www.nrl.navy.mil

U.S. Department of Veterans Affairs, Office of Research and Development
http://www.va.gov/oro/

Walter Reed Army Institute of Research
http://www.wrair.army.mil/

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 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 in which the VA investigator has a substantial role in the research, or by advertising to the general public.

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 (see definition of clinical trial above). 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 agencies 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

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

- Initiating PI should be at or above the level of Assistant Professor or equivalent. Post-doctoral fellows are not eligible to be Partnering PIs.
- The partnering PI(s) must be at or above the level of Assistant Professor (or equivalent).
- ***It is encouraged that at least one of the PIs be a military or VA investigator.***
- 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 **3** years.
- The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and each Partnering PI's applications will not exceed **$1,000,000**. The combined total direct costs of Initiating PI and each Partnering PI's awards will not exceed **$1,000,000** direct costs. If the Initiating PI's or any Partnering PI's budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed **$1,000,000** or use an indirect rate exceeding each 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 **3** years.
- A separate award will be made to each PI's organization.
- The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.

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

- Salary
- Research supplies
- Clinical research costs. ***Funding for clinical trials is not allowed.***
- Travel between collaborating organizations
- Travel costs for up to 3 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 $16M of the $50M FY16 PRCRP appropriation to fund approximately 10 Translational Team Science Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission 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.

The Translational Team Science Award mechanism is structured to accommodate multiple (at least two, and up to three) PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. ***Each Partnering PI must follow the link in this email in order to associate his/her Grants.gov application package with that of the Initiating PI.*** If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Do not delay completing these steps. If they are not completed, the Partnering PI(s) will not be able to view and modify his/her application during the verification period in eBRAP.

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-TTSA 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 Initiating 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).

The Initiating PI is responsible for submission of all pre-application components.

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.
  - 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 pre-application or application. For questions related to 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.
  - The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.
  - 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 (three-page limit): The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. 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.

  Correlative clinical research studies are allowed under this mechanism. Funding for clinical trials is not permitted.

  The Preproposal Narrative should include the following:

  - **Collaboration:** Identify roles and responsibilities of each translational team member, including the military or VA investigator (if applicable). Describe how the project depends on the unique skills of each partner. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
  - **Research Objectives and Rationale:** Identify the critical knowledge gaps, key research and potential transformative findings, or novel outcomes from an ongoing or completed clinical trial to be studied. Concisely state the hypothesis, the project's objectives, specific aims, and experimental design. Briefly describe how the preliminary data supports the rationale and the project's objectives. Describe how the project will leverage information from ongoing or completed clinical trials to address knowledge gaps in resulting outcomes or clinical observations.
  - **Translation:** Describe the reciprocal transfer of information between basic and clinical science in developing, implementing, and moving the proposed research into clinical applications in at least one of the FY16 PRCRP Topic Areas in Section I.B.
  - **Military Relevance and Impact:** State which of the FY16 PRCRP Military Relevance Focus Areas in Section I.C. the study addresses and how the study will benefit Service members, their families, Veterans, or other military beneficiaries.
  - **Innovation:** Describe how the research introduces a new paradigm, challenges existing paradigms, or looks at resulting clinical outcomes from new perspectives.

  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.
  - Include biographical sketches for Initiating PI and Partnering PI(s).
- Key Personnel Previous/Current/Pending Support.
  - Include previous/current/pending support for Initiating PI and Partnering PI(s).

- **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 PRCRP, pre-applications will be screened based on the following criteria:

  - **Collaboration:** How the roles and responsibilities of the translational team, including the military or VA investigator (if applicable), integrate to form synergy between laboratory science and the clinic. How well the project depends on the unique skill set of each partner. Whether the proposed collaboration involves a substantial contribution by each partner and shows the reciprocal flow of ideas and information.
  - **Research Objectives and Rationale:** Whether the study is hypothesis-driven. Whether the research addresses critical knowledge gaps, key research and potential transformative findings, or novel outcomes. How well the project's objectives, specific aims, and experimental design are based on preliminary data and derived from an ongoing or completed clinical trial and/or translational research. Whether the project leverages information from ongoing or completed clinical trials and addresses knowledge gaps in the resulting outcomes.
  - **Translation:** Whether there is a reciprocal transfer of information between basic and clinical science in developing, implementing, and moving the proposed research into clinical applications in at least one of the FY16 PRCRP Topic Areas in Section I.B.
  - **Military Relevance and Impact:** Whether a FY16 PRCRP Military Relevance Focus Areas in Section I.C. is addressed. To what degree the study will benefit Service members, their families, Veterans, and other military beneficaries.

- **Innovation:** Whether the study proposes a new paradigm, challenge existing paradigms, or looks at resulting clinical outcomes from new perspectives.

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

  Following the pre-application screening, Initiating 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 Initiating PI has received notification of invitation.

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

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/). For the Translational Team Science Award, additional application components are also required and should be submitted as directed below.

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 CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each Grants.gov application package must be submitted using the unique eBRAP log number. ***Note: All associated***

applications (Initiating and each Partnering PI) must be submitted by the Grants.gov 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 Translational Team Science Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **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 (twelve-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.

     - **Background:** Present the ideas and reasoning behind the proposed research. Describe the ongoing or completed clinical trial or translational research to be leveraged, the gaps in that study, and how this proposed study will address the gaps and build on the original study. Describe the clinical outcomes or translational research results most pertinent to this application. Preliminary data such as published or unpublished results from the laboratory and/or clinic of the Initiating PI, Partnering PI(s), or collaborators named on this application and/or data from the published literature relevant to the proposed research project must be included to support the hypothesis or objectives.

     - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

- **Specific Aims:** Concisely explain the project's specific aims. If this research project is a correlative study to an ongoing clinical trial, present ***only*** the tasks that the DoD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses in sufficient detail for evaluation including availability of resources (if applicable). Include details on outcomes or results from the clinical trial or translational research upon which this project will be based. Include preliminary data and reconcile it with objectives of the research proposed. Include how proposed research addresses an important clinical and/or translational question relevant to at least one of the FY16 PRCRP Topic Areas in Section I.B. and FY16 PRCRP Military Relevance Focus Areas in Section I.C. Address potential problem areas, potential pitfalls, and present alternative methods and approaches. 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.

- 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. Describe the clinical and/or translational outcomes upon which the study is founded.
- **Hypothesis/Objective:** State the hypothesis to be tested and the objective to be reached. Describe the overall research goals.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design including appropriate controls.
- **Collaboration/Translational Aspects:** Describe how the project depends on the unique skills of each partner. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information. Demonstrate how the translational collaboration will maximize the use of existing resources and minimize unnecessary duplication.
- **Military Relevance and Impact:** Identify the FY16 PRCRP Military Relevance Focus Area(s) to be studied. Briefly describe how the proposed research is relevant to active duty Service members, their families, Veterans, and other military beneficiaries. Describe how the research will accelerate the movement of promising ideas (in prevention, diagnosis, detection, prognosis, treatment, and survivorship) in one of the FY16 PRCRP Topic Areas into clinical applications.
- **Innovation:** Briefly describe how the proposed project is innovative and represents a new paradigm, challenges existing paradigms, or looks at existing problems from new perspectives.

- **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 use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

  - State the hypothesis to be tested. Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine***.
  - Describe the ultimate applicability of the research.
    - What types of patients will it help, and how will it help them?

    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a patient-related outcome?
    - What are the likely contributions of this study to advancing one of the FY16 PRCRP Topic Areas in Section I.B?
  - Describe how the proposed research will benefit Service members, their families, Veterans, and/or 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 Translational Team Science Award 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.

  Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.

- **Attachment 6**: **Collaboration Plan (two-page limit): Upload as "CollabPlan.pdf."**
  - Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and organizations participating in the project.
  - Describe the roles, responsibilities, and intellectualcontribution of each member of the team in the proposed research. Describe how the project depends on the unique skills of each partner. Provide the time commitment for each partner. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
    - Describe the role and responsibility of the Military or VA investigator in the overall research project (if applicable).
  - Include information on meetings and coordination of decision-making processes over multi-institutions if applicable.

- **Attachment 7: Transition Plan (one-page limit): Upload as "Transition.pdf."** Describe the methods and strategies proposed to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the award. The post-award transition plan should include the components listed below.
  - The development and/or commercialization strategy, if applicable.
  - Details of the funding strategy to transition to the next level of investigation, development and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for).

- For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development. A "Knowledge Product" is a non-materiel product that addresses an identified need, topic area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities), and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
- A schedule and milestones for transitioning the anticipated research outcomes to the next level of development (next-phase clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA).
- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government's ability to access such products or technologies in the future.

- **Attachment 8**: **Translation Statement (one-page limit): Upload as "Translation.pdf."**
  - Describe the translational aspects and potential of the proposed research.
  - Explain the significance of the translational value of the proposed work based on clinical and/or translational research outcomes, or current treatment and care options.

- **Attachment 9: Military Relevance 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; and/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 Service members, their families, Veterans, and other military beneficiaries or mission readiness for active duty military.
  - 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 10: 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 11: 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 proposed research goals, if achieved, would fit into that pathway.

  Attachment 12: Letters Confirming Access to Target Military or VA Patient Population(s) or Resources (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 13: 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 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 14: 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."
     - Include biographical sketches for the Partnering PI(s).
   - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
     - Include previous/current/pending support for the Partnering PI(s).

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.
   - ***Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI(s), even if they are located within the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and each Partnering PI's***

applications will not exceed $1,000,000. The combined total direct costs of the Initiating and Partnering PIs' awards will not exceed $1,000,000 direct costs. If the Initiating or any Partnering PI's budget contains a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed $1,000,000 or using an indirect rate exceeding each organization's negotiated rate.

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 14, 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.

Application Components for the Partnering PI(s):

Each Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate his/her Grants.gov application package with that of the Initiating PI.

The application submission process for Partnering PI(s) uses an abbreviated Grants.gov application package that includes:

1. **SF424 (R&R) Application for Federal Assistance Form**

2. **Attachments Form**

   - **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C.2., for detailed information on completing the SOW. ***Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating and Partnering PIs should be noted for each task.***

3. **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."

- ***Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are at the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating and Partnering PIs' applications will not exceed $1,000,000. The combined total direct costs of the Initiating and Partnering PIs' awards will not exceed $1,000,000 direct costs. If the Initiating or any Partnering PI's budget contains a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed $1,000,000 or use an indirect rate exceeding each organization's negotiated rate.***

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

5. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.5., for detailed information.

   Collaborating DoD Military Facilities Form: Refer to the General Application Instructions, Section II.C.7., for detailed information. The costs per year should be included on the Grants.Gov Research and Related Budget form under subaward costs.

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 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:

- **Research Strategy and Feasibility**
  - How well the proposed research addresses an important clinical and/or translational question relevant to at least one of the FY16 PRCRP Topic Areas in Section I.B.
  - How well the rationale, experimental design, and methodology are appropriate to test the hypothesis and reach the final objective.
  - If applicable, to what extent the human subject population described is appropriate for the study and there is clear demonstration of access to the designated population.
  - To what degree the statistical plan is appropriate for the experimental methodology being used. Whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed.
  - To what degree the preliminary data and/or clinical and/or translational research outcomes supports the foundation of the research.
  - How well the PIs acknowledge potential problems, potential pitfalls, and addresses alternative approaches.
  - Whether the applicants demonstrate the availability of tissue, data, or human subjects, if applicable.
  - How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used, if applicable.
- **Translational Potential**
  - How well the project will translate promising clinical trial and/or translational research findings into clinical applications.
  - Whether the project will leverage results from an ongoing or completed clinical trial to further clinical applications or translational potential.
- **Innovation**
  - To what degree the proposed research is innovative (e.g., 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).
- **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.

- **Personnel and Collaboration**
  - To what degree each PI has the research experience to function as a partner in a collaborative project.
  - The extent to which each PI, including the military or VA investigator (if applicable), will contribute substantially to the development and implementation of the research plan and to the reciprocal flow of information.
  - How the research team's backgrounds are appropriate to study the specified FY16 PRCRP Topic Area(s) in Section I.B., with respect to the team's ability to perform the proposed work.
  - To what degree the levels of effort are appropriate for the successful completion of the proposed research.
- **Transition Plan**
  - To what extent the proposed plan for the next level of development or commercialization is achievable.
  - Whether the funding strategy described to bring the anticipated research outcomes to the next level of development is reasonable and realistic.
  - To what degree the proposed collaborations and other resources for providing continuity of development are established and/or achievable.
  - Whether the schedule and milestones for bringing the technology or Knowledge Product to the next level of are achievable.
  - Whether the applicants have demonstrated that they have access to all intellectual property rights necessary for the next level of development or commercialization, and if not, whether a plan for management of intellectual property is in place including the Government's ability to access such products or technologies in the future.

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

- **Environment**
  - To what degree the scientific environments are appropriate for the proposed research.
  - To what degree the research requirements are supported by the availability of and accessibility to facilities and resources.
  - To what degree the quality and extent of institutional support are appropriate.
- **Budget**
  - Whether the maximum direct costs are equal to or less than the allowable maximum direct 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 Initiating PI or the Partnering PI(s).
  - **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

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 exceeds page limit.
- Preproposal Narrative is missing.

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 Preproposal Narrative and 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.
- 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., then the pre-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.
- If all associated (Initiating and Partnering PIs) applications are not submitted by the deadline, the application may 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 supporting the Initiating or Partnering PI is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer. 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	Initiating PI Completed	Partnering PI 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	Collaboration Plan: Upload as Attachment 6 with file name "CollabPlan.pdf."		
	7	Transition Statement: Upload as Attachment 7 with file name "Transition.pdf."		
	8	Translation Statement: Upload as Attachment 8 with file name "Translation.pdf."		
	9	Military Beneficiaries Relevance and Impact Statement: Upload as Attachment 9 with file name "MilBen.pdf."		
	10	Innovation Statement: Upload as Attachment 10 with file name "Innovation.pdf."		
	11	Impact Statement: Upload as Attachment 11 with file name "Impact.pdf."		
	12	Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s) (e.g., Human/Animal Anatomical Substances, Databases): Upload as Attachment 12 with file name "Access.pdf," *if applicable.*		
	13	Use of Hazardous Chemical or Biological Agents: Upload as Attachment 13 with file name "Hazardous.pdf," *if applicable.*		
	14	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 14 with file name "MFBudget.pdf," *if applicable.*		

Grants.gov Application Components	Upload Order	Action	Initiating PI Completed	Partnering PI Completed
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 form 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.		