I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Translational Team Science Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-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 30, 2017
- **Invitation to Submit an Application:** August 3, 2017
- **Application Submission Deadline:** 11:59 p.m. ET, September 28, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, October 5, 2017
- **Peer Review:** November 2017
- **Programmatic Review:** February 2018

This Program Announcement must be read in conjunction with the General Application Instructions version 20170516. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2017 (FY17) Peer Reviewed Cancer Research Program (PRCRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The PRCRP was initiated in 2009 to provide support for research of exceptional scientific merit and is managed by the CDMRP. Appropriations for the PRCRP from FY09 through FY16 totaled $199.8 million (M). The FY17 appropriation is $60M.

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, other military beneficiaries, and the American public.

II.A.1. FY17 PRCRP Topic Areas

To be considered for funding, applications for the FY17 PRCRP Translational Team Science Award (TTSA) ***must*** address at least one of the FY17 PRCRP Topic Areas as directed by Congress. Research applications in the areas of breast, prostate, lung (excluding mesothelioma), kidney, or ovarian cancer will ***not*** be accepted. The FY17 PRCRP Topic Areas are listed below.

- Bladder cancer
- Brain cancer ***(new for FY17)***
- Colorectal cancer
- Immunotherapy[*]
- Listeria-based regimens for cancer
- Liver cancer
- Lymphoma
- Melanoma and other skin cancers
- Mesothelioma
- Neuroblastoma
- Pancreatic cancer
- Pediatric brain tumors
- Stomach cancer
- Cancer in children, adolescents, and young adults[†] ***(new for FY17)***

[*] As derived from the National Cancer Institute Dictionary of Cancer terms (https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=45729). Immunotherapy is a biological therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer.
[†]The definition of adolescents and young adults is derived from the National Cancer Institute (https://www.cancer.gov/types/aya) and can be considered to be people between the ages of 15-39 years.

II.A.2. FY17 PRCRP Military Relevance Focus Areas

In addition to addressing at least one of the required FY17 PRCRP Topic Areas in Section II.A.1, applications for the FY17 PRCRP TTSA ***must*** also address at least one of the FY17 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 FY17 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 active duty Service members, Veterans, and their beneficiaries.

For more information on military-related exposures and risk factors for cancer refer to: Military Relevance Specific to Cancer(s) (http://www.publichealth.va.gov/exposures/health-concerns.asp) or 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.

II.B. Award Information

The FY17 PRCRP TTSA supports ***hypothesis-driven*** translational studies. These studies should be associated with an ***ongoing or completed*** clinical trial and/or annotated biorepositories and focused on research for the next-phase clinical trial or future clinical application. The TTSA is intended to support advanced translational studies that have the potential for near-term outcomes that are based on results from clinical investigations. While funding for clinical trials is allowed, the TTSA is intended to fund correlative clinical research studies and not only a clinical trial. Research projects funded by the TTSA should address critical knowledge gaps in clinical outcomes, validate key research results, expand upon potentially transformative results, or investigate novel findings based on results from clinical research.

New for FY17: The FY17 PRCRP TTSA encourages studies investigating:

- Patient-reported outcomes, survivorship, and/or quality of life

- Precursor lesions of metastatic disease

- Differences in prognosis and response to treatment with respect to primary nodal status

- The relationship between prevention and longitudinal cancer risk outcomes

- Tumor heterogeneity (e.g., genetic, epigenetic, immunological) and its association to the tumor microenvironment

The TTSA may support studies in animal models, 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.

Important aspects of the TTSA mechanism 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, Principal Investigators (PIs) must partner in one overarching study in at least one of the required FY17 PRCRP Topic Areas in Section II.A.1.*** 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 defined as an investigator who is 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).

- **Translation:** 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, annotated biorepositories, or translational research. The application should demonstrate how the study will leverage clinical information to address knowledge gaps in resulting outcomes, validate key research findings, and expand upon potentially transformative results, or investigate novel findings.

- **Military Relevance:** ***The proposed research must address at least one of the FY17 PRCRP Military Relevance Focus Areas in Section II.A.2.*** The proposed research must be relevant to active duty Service members, 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. Studies into cancer knowledge gaps that may affect an individual's mission readiness, patient care, and treatment options are critical. 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), VA (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 the potential to have a significant impact on cancer research and/or patient care, and have the potential to accelerate the movement of promising ideas (in prevention, diagnosis, detection, prognosis, treatment, and/or survivorship) into clinical applications for at least one of the FY17 PRCRP Topic Areas in Section II.A.1.

- **Preliminary Data Required:** Clinical data must be included in the application and/or citations of the investigators' work that are relevant to the proposed studies.

The anticipated direct costs budgeted for the entire period of performance for an FY17 PRCRP TTSA will not exceed **$1,000,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

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

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

Cancer clinical research resources: PIs are encouraged to review clinical research and/or trial information and resources available through the National Cancer Institute, Cancer Therapy Evaluation Program (CTEP). Detailed information on the activities of the CTEP can be found through the following links:

- NCI's National Clinical Trials Network (NCTN):
  http://www.cancer.gov/research/areas/clinical-trials/nctn
- Experimental Therapeutics Clinical Trials Network (ETCTN):
  https://ctep.cancer.gov/initiativesPrograms/etctn.htm

- Adult Brain Tumor Consortium (ABTC)
  https://ctep.cancer.gov/MajorInitiatives/Adult_Brain_Tumor_Consortium.htm

- Blood and Marrow Clinical Trials Network (BMT CTN):
  https://ctep.cancer.gov/branches/cgcb/blood_and_marrow_clinical_trials_network.htm

- Cancer Immunotherapy Trials Network (CITN):
  https://ctep.cancer.gov/MajorInitiatives/cancer_immunotherapy_trials_network.htm

- Pediatric Brain Tumor Consortium (PBTC):
  https://ctep.cancer.gov/investigatorResources/childhood_cancer_resources.htm

- Pediatric Preclinical Testing Consortium (PPTC):
  https://ctep.cancer.gov/MajorInitiatives/Pediatric_Preclinical_Testing_Consortium.htm

The FY17 PRCRP TTSA mechanism requires ***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 a Partnering PI(s). Initiating and Partnering PIs each have different submission requirements, as described in Section II.D.2, Content and Form of the Application; 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. If recommended for funding, each applicant 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.

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 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 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***. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded project will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

Clinical trials are allowed. A clinical trial is defined as a prospective accrual of patients (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested 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 the clinical trial involves the use of a drug that has not been approved by the U.S. Food and Drug Administration (FDA) for the proposed investigational use, evidence that an Investigational New Drug (IND) exemption application that meets all requirements under the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312) has been submitted or will be submitted to the FDA ***within 60 days of award*** is required. If the investigational product is a device, evidence that an Investigational Device Exemption (IDE) application that meets all requirements under 21 CFR 812 has been submitted or will be submitted to the FDA ***within 60 days of award***, or that the device is exempt from an IDE, is required. The Government reserves the right to withdraw funding if the IND or IDE application has not been submitted to the FDA within 60 days of the DoD award date or if the documented status of the IND or IDE has not been obtained within 6 months of the award date.

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 1, 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 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 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to Section II.F.1, Federal Award Notices.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.

Government Agencies within the United States: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission: Application submitted by a non-DoD organization to Grants.gov.*

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. *Intramural Submission: Application submitted by a DoD organization for an intramural investigator who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.*

Note: Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

The Initiating PI must be at or above the level of Assistant Professor or equivalent.

The Partnering PI(s) must be at or above the level of Assistant Professor or equivalent. Postdoctoral fellows are not eligible to be Partnering PIs.

It is encouraged that at least one of the PIs be a military or VA investigator.

FY17 PRCRP Programmatic Panel members are ineligible to apply and may not be named as a participant on an application.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by or affiliated with an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at http://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Extramural organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

There are no limitations on the number of applications for which an investigator may be named as an Initiating PI or a Partnering PI.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and 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).

Extramural Submission is defined as an application submitted by a non-DoD organization to Grants.gov.

Intramural Submission is defined as an application submission by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

II.D.1. Address to Request Application Package

Submitting Extramural and Intramural Organizations: Pre-application content and forms can be accessed at the eBRAP (https://eBRAP.org).

Submitting Extramural Organizations: Full application packages can be accessed at Grants.gov.

Submitting Intramural DoD Organizations: Full application packages can be accessed at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both ***pre-application*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

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.

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be through Grants.gov. Applications submitted by extramural organizations (e.g., research

foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.Gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

eBRAP also allows intramural organizations to submit full applications following pre-application submission.

For both Extramural and Intramural Applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement 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.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate 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.

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 full application package with that of the Initiating PI. After following the link, each Partnering PI must verify his/her contact information, organization, and designation as an extramural or intramural submission within eBRAP.*** 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.

II.D.2.a. Step 1: Pre-Application Submission Content

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 full application submission process.

To begin the pre-application process, first select whether the organization is an extramural or intramural applicant, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type may result in delays in processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

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

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

- **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 be either 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 be either 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. The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.

  FY17 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 II.H.2.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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, 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). Pre-applications or 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

  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 the General Application Instructions, Appendix 3, Section C, 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.

    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 potentially transformative findings, or novel outcomes from an ongoing or completed clinical research or trial to be studied. Concisely state the hypothesis, the project's objectives, specific aims, and experimental design. Briefly describe how the preliminary data support the rationale and the project's objectives. Describe the correlative clinical research objectives and goals. Describe how the project will leverage information from ongoing or completed clinical trials or other clinical data to address knowledge gaps in clinical observations. *If applicable*, state how the proposed research will address the FY17 PRCRP TTSA encouraged areas of study in Section II.B.

- **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 FY17 PRCRP Topic Areas in Section II.A.1.

- **Military Relevance and Impact:** State which of the FY17 PRCRP Military Relevance Focus Areas in Section II.A.2 the study addresses and how the study will benefit active duty Service members, Veterans, or other military beneficiaries.

- **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 the following:

  - 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, reference title, and reference source, including 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 PRCRP, pre-applications will be screened based on the following criteria:

- **Collaboration:** How the roles and responsibilities of each translational team member, 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 potentially transformative findings, or novel outcomes from ongoing or completed research. 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 research objectives and goals are described according to the intent of the TTSA (see Section II.B, Award Information). Whether the project leverages clinical information and addresses knowledge gaps in the resulting outcomes. How the proposed research will address the FY17 PRCRP TTSA encouraged areas of study, if applicable.

- **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 FY17 PRCRP Topic Areas in Section II.A.1.

- **Military Relevance and Impact:** Whether at least one of the FY17 PRCRP Military Relevance Focus Areas in Section II.A.2 is addressed. To what degree the study will benefit active duty Service members, Veterans, and other military beneficiaries.

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 time frame for notification of invitation to submit an application is indicated in Section I, Overview of the Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

II.D.2.b. Step 2: Full Application Submission Content

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. Refer to the General Application Instructions, Section III, 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 full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (http://www.grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines. For the TTSA, additional application components are also required and should be submitted as directed in the Application Components for the Partnering PI(s) section.

II.D.2.b.i. Full Application Guidelines

Extramural organizations, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-17-PRCRP-TTSA from Grants.gov (http://www.grants.gov)	Download application package components for W81XWH-17-PRCRP-TTSA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components • Attachments • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • R&R Subaward Budget Attachment(s) Form (if applicable) • Additional Application Component(s)	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components. • Attachments • Key Personnel • Budget • Performance Sites • Other **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.

Extramural Submissions	Intramural DoD Submissions
Application Package Submission	
Submit package components to Grants.gov (http://www.grants.gov). If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need 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.	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PI(s) will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.
Further Information	
Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

The organization's Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

Application viewing, modification, and verification in eBRAP are 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.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

The CDMRP requires separate full application package submissions for the Initiating PI and Partnering PI(s), even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. ***Note: All associated applications (Initiating and Partnering PIs') must be submitted by the full application submission deadline.***

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

II.D.2.b.ii. Full Application Submission Components

- **Extramural Applications Only –**

  SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1., for detailed information.

- **Extramural and Intramural Applications –**

  Attachments:

  Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in Appendix 4 of the General Application Instructions.

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are 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, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full application package may not exceed 200 MB.

  - **Attachment 1: Project Narrative (12-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) 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 required.***

    - **Background:** Present the ideas and reasoning behind the proposed research. Describe the ongoing or completed clinical trial or translational research to be leveraged, the knowledge 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. Describe the proposed research objectives and goals.

- **Specific Aims:** Concisely explain the project's specific aims. If this research project is a correlative study to an ongoing or completed clinical trial, present ***only*** the tasks that this 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 the proposed research addresses an important clinical and/or translational question relevant to at least one of the FY17 PRCRP Topic Areas in Section II.A.1 *and* at least one of the FY17 PRCRP Military Relevance Focus Areas in Section II.A.2. If applicable, state how the proposed research will address the FY17 PRCRP TTSA encouraged areas of study in Section II.B. 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, or clinical research involving 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. ***If funds for a clinical trial are requested, details regarding the Clinical Strategy should be outlined in Attachment 11.***

- **Attachment 2: Supporting Documentation.** Combine and upload as a single file named "Support.pdf." Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

  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, 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. 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.

- Intellectual Property: Information can be found in 2 CFR 200.315, "Intangible Property."

  - 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 2, 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 FY17 PRCRP Topic Area(s) in Section II.A.1 to be addressed by the proposed research. State the FY17 PRCRP Military Relevance Focus Area(s) in Section II.A.2 to be addressed. Present the ideas and reasoning behind the proposed work. Describe the clinical and/or translational research 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 FY17 PRCRP Military Relevance Focus Area(s) to be studied. Briefly describe how the proposed research is relevant to active duty Service members, Veterans, and other military beneficiaries. Describe how the research will accelerate the movement of promising ideas (in prevention, diagnosis, detection, prognosis, treatment, and/or survivorship) in one of the FY17 PRCRP Topic Areas into clinical applications.

- **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 FY17 PRCRP Topic Area(s) in Section II.A.1 *and* Military Relevance Focus Area(s) in Section II.A.2 to be 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? What is the projected time it may take to achieve a patient-related outcome? What are the likely contributions of this study to advancing at least one of the FY17 PRCRP Topic Areas in Section II.A.1?

- Describe how the proposed research is relevant to active duty Service members, 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 TTSA mechanism, use the SOW format example titled "SOW (Statement of Work) Generic Format." The SOW must be in PDF format prior to attaching.

  The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

  Include the name(s) of the key personnel and contact information for each study site/ subaward site.

  Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory review.

  Briefly state the methods to be used.

  For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

  Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

  If applicable, indicate timelines required for regulatory approvals relevant to human subjects review (e.g., IND and IDE) by the FDA or other Government agency.

  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 intellectual contribution 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).

- **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 (e.g., 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: Relevance to Military Beneficiaries Statement (one-page limit):** Upload as "MilBen.pdf." ***The Relevance to Military Beneficiaries Statement will be evaluated by the FY17 PRCRP Programmatic Panel during programmatic review only.***
  - State the FY17 PRCRP Topic Area(s) in Section II.A.1 to be addressed in the study.
  - Identify the militarily relevant risk factors associated with the FY17 PRCRP Military Relevance Focus Area(s) in Section II.A.2 to be studied and their short- and long-term impact on the health, welfare, and/or psychosocial wellness of active duty Service members, Veterans, and other military beneficiaries.

    or

  - Identify the knowledge 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 active duty Service members, 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 active duty Service members, 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 active duty Service members, Veterans, and other military beneficiaries.
  - Describe how the study design will replicate field conditions, if appropriate. If active duty Service members, military families, or 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 Veteran population).
- **Attachment 10: 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 FY17 PRCRP Topic Areas in Section II.A.1. 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 11: Clinical Strategy Statement, *if applicable*:** Upload as "Clinical.pdf." **If funds for a clinical trial are requested, this attachment is required.** Describe the rationale for the proposed clinical trial. Provide a description of the intervention, the endpoints to be measured. Provide detailed plans for initiating the clinical study within the first year, including FDA IND/IDE application submission plans within 60 days of the award, *if applicable*. Indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria. Provide a detailed statistical plan, to include power analysis. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate. Describe how the clinical trial will inform the correlative clinical research. Describe the data management plans. If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically identify the portions of the study that would be supported with funds from this award. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- **Attachment 12: 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 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 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 14: DoD Military 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 DoD Military 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 III.A.7, for detailed information.

- **Extramural and Intramural Applications –**

  Research & Related Senior/Key Person Profile (Expanded). For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3 and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2 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 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.

  - 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).

- **Extramural and Intramural Applications –**

  Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4 and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3 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 his/her own portion of the efforts as part of his/her separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s), even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

- **Extramural and Intramural Applications –**

  Project/Performance Site Location(s) Form). For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

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

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)

  - **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 14. (Refer to the General Application Instructions, Section IV.A.3 for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

  DoD Military Budget Form: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) 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 DoD Military Budget Form (Attachment 14) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.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 full application package with that of the Initiating PI.

For each Partnering PI, the Initiating PI must identify if that Partnering PI will be submitting an extramural or intramural application (in accordance with the guidelines in Section II.C.1.a, Organization) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). Each Partnering PI must verify his/her contact information and mode of submission within eBRAP to ensure proper submission of his/her application.

The application submission process for the Partnering PI(s) uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications –**

  Attachments

  - **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section III.A.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 PI and Partnering PI(s) should be noted for each task.

  - **Attachment 14: DoD Military Budget Form:** Upload as "MFBudget.pdf." Refer to the General Application Instructions, Section III.A.7, for detailed information. The costs per year should be included on the Grants.Gov Research and Related Budget form under subaward costs.

  Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section III.A.4, and for intramural submissions, refer to the General Application Instructions, Section IV.A.3 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 his/her own portion of the efforts as part of his/her 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 located within the same organization. Refer to Section II.D.5, Funding Restrictions for detailed information.

  Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to General Application Instructions, Section IV.A.4 for detailed information.

- **Extramural Applications Only –**

  R&R Subaward Budget Attachment(s) Form.

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)

  - **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to eBRAP as Attachment 14. (Refer to the General Application Instructions, Section III.A.7, for detailed information.)

II.D.3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM)

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. Verify the status of the applicant's organization's Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application 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 a submitted application. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement 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. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

II.D.5. Funding Restrictions

The maximum period of performance is **4** 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 all Partnering PIs' awards will not exceed **$1,000,000** direct costs. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. 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 cost rate exceeding each organization's negotiated rate.

All direct and indirect costs of any subaward or contract 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 **4** 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
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for up to three investigators to travel to two scientific/technical meetings per year

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators. Application packages from associated extramural partnering PIs will be funded through assistance agreements.

Refer to the General Application Instructions, Section III.A.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 the General Application Instructions, Section III.A.4.***

The CDMRP expects to allot approximately $16M of the $60M FY17 PRCRP appropriation to fund approximately 10 TTSA applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. 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 FY17 PRCRP Topic Areas in Section II.A.1.
    - 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 support the proposed research.
    - How well the proposed research addressed an FY17 PRCRP TTSA encouraged area of study in Section II.B, if applicable.
    - 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.
- **Clinical Strategy (as applicable for applications proposing a clinical trial)**
    - How well the applicant describes the access to the study population, recruitment plan, and inclusion/exclusion criteria.
    - Whether the proposed intervention is feasible and endpoints are rational.
    - Whether plans for initiating the clinical trial within the first year are described.

- Whether the FDA IND/IDE application submission plans are within the scope of submitting within 60 days of the award date and are feasible.
- Whether the proposed clinical trial has sound rationale, methodology, and whether a description of the type of clinical trial to be performed (e.g., prospective, randomized, controlled) is provided.
- To what degree the potential challenges and alternative strategies for the proposed clinical trial are described.
- To what degree the statistical plan is appropriate for the proposed clinical trial.
- Whether the clinical trial is designed with enough statistical power to lead to meaningful results.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

- **Personnel and Collaboration**
  - To what degree each PI has the research experience to function as a partner in the proposed 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 FY17 PRCRP Topic Area(s) in Section II.A.1, 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.
- **Impact**
  - How well the proposed research addresses a critical problem and/or patient care in at least one of the FY17 PRCRP Topic Areas in Section II.A.1.
  - 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 FY17 PRCRP Topic Areas in Section II.A.1.
- **Translational Potential**
  - To what degree the proposed research objectives and goals will translate the anticipated research outcomes into clinical applications.

- Whether the project will leverage results from prior clinical research to further their clinical applications or translational potential.

- **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.

  - Whether the budget is appropriate for the proposed research.

  - Whether there may be significant overlap with existing or pending awards of the Initiating PI or the Partnering PI(s).

  - If applicable, whether the application clearly indicates the funding of the proposed clinical trial.

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

II.E.1.b. 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:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY17 PRCRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Military relevance
    - Relative impact

II.E.2. 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 Commanding General, USAMRMC, on behalf of the DHA 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. 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 II.E.1.b, 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 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold (currently $150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant, at his/her option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about him/herself that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in Section I, Overview of the Funding Opportunity.

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.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural organizations: An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a "thing of value," to a "state, local government," or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement

on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing documents.

Intramural Organizations: Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers (RM).

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI's organization.

II.F.1.a. Award Transfers

An organizational transfer of an award supporting the Initiating PI or any of the Partnering PI is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer.

The organization transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis 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 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGAR found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

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

Refer to full text of the USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations and the USAMRAA General Research Terms and Conditions with For-Profit Organizations for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements.

Quarterly technical progress reports will be required.

Annual Award Charts will be required. For the TTSA mechanism, use the format example titled "Generic Award Charts," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). During the period of performance, progress on the research project will be summarized in individual annual Award Charts that will be required from the Initiating PI as well as the Partnering PI(s). The study goals and specific aims should be the same, but the research accomplishments should indicate the work performed by each PI.

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations is available in OAR Article I, Section B, in the July 2016 R&D General Terms and Conditions. The applicable Terms and Conditions for for-profit organizations are available in Section 34 of the February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations.

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission 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

II.G.2. Grants.gov Contact Center

Questions related to extramural 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 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.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Version

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20170516a. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

II.H.2. Administrative Actions

After receipt of pre-applications or applications, the following administrative actions may occur:

II.H.2.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.

II.H.2.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.

II.H.2.c. Withdrawal

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

- An FY17 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 FY17 PRCRP Programmatic Panel members can be found at http://cdmrp.army.mil/prcrp/panels/panels17***.

- The application fails to conform to this Program Announcement 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 FY17, 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, 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.

- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.

- Applications submitted by an intramural DoD organization may be withdrawn if the intramural DoD organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds as subawards or contracts to extramural collaborators.

- Applications may be administratively withdrawn from further consideration if the applicant cannot demonstrate access to the relevant study population or resources.

- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.
- The invited application does not propose the same research project described in the pre-application.
- 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 FY17 PRCRP Topic Areas in Section II.A.1, the pre-application or application will be withdrawn.
- If the pre-application or application does not address at least one of the FY17 PRCRP Military Relevance Focus Areas in Section II.A.2, the pre-application or application will be withdrawn.
- If the pre-application or application proposes breast, prostate, lung (excluding mesothelioma), kidney, or ovarian cancer research, the pre-application or application will be withdrawn.
- All associated (Initiating PI and Partnering PI(s)) applications are not submitted by the deadline.

II.H.2.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.

II.H.3. Application Submission Checklist

Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF424 (R&R) Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed.		
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete these tabs as instructed.		
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."		
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."		
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."		
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	Collaboration Plan: Upload as Attachment 6 with file name "CollabPlan.pdf."		
	Transition Statement: Upload as Attachment 7 with file name "Transition.pdf."		
	Translation Statement: Upload as Attachment 8 with file name "Translation.pdf."		
	Relevance to Military Beneficiaries Statement: Upload as Attachment 9 with file name "MilBen.pdf."		
	Impact Statement: Upload as Attachment 10 with file name "Impact.pdf."		
	Clinical Strategy Statement: Upload as Attachment 11 with file name "Clinical.pdf," if applicable.		
	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.		

Application Components	Action	Initiating PI Completed	Partnering PI Completed
	Use of Hazardous Chemical or Biological Agents: Upload as Attachment 13 with file name "Hazardous.pdf," if applicable.		
	DoD Military Budget Form(s): Upload as Attachment 14 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 **(Extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Budget **(Intramural submissions only)**	Complete the DoD Military Budget Form and Justification.		
Project/Performance Site Location(s) Form	Complete form as instructed.		
R&R Subaward Budget Attachment(s) Form	Complete form as instructed.		

APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting In Vivo Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
PRCRP	Peer Reviewed Cancer Research Program
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management
SOW	Statement of Work
TTSA	Translational Team Science Award
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs