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-19-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), May 22, 2019
- **Invitation to Submit an Application:** June 26, 2019
- **Application Submission Deadline:** 11:59 p.m. ET, September 11, 2019
- **End of Application Verification Period:** 5:00 p.m. ET, September 16, 2019
- **Peer Review:** November 2019
- **Programmatic Review:** January 2020

This Program Announcement must be read in conjunction with the General Application Instructions, version 20190218. The General Application 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 2019 (FY19) 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 for the benefit of Service members, their families, and the American public. Appropriations for the PRCRP from FY09 through FY18 totaled $339.8 million (M). The FY19 appropriation is $90M.

The goal of the PRCRP is to improve mission readiness and quality of life by decreasing the burden of cancer on 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. FY19 PRCRP Topic Areas

To be considered for funding, applications for the FY19 PRCRP Translational Team Science Award ***must*** address at least one of the FY19 PRCRP Topic Areas as directed by Congress. Research applications in the areas of breast, prostate, lung (excluding mesothelioma), kidney, melanoma, or ovarian cancer will ***not*** be accepted. The FY19 PRCRP Topic Areas are listed below.

- Bladder cancer
- Blood cancers
- Brain cancer
- Cancer in children, adolescents, and young adults[1]
- Colorectal cancer
- Immunotherapy[2]
- Listeria vaccine for cancer
- Liver cancer
- Lymphoma
- Mesothelioma
- Neuroblastoma
- Pancreatic cancer
- Pediatric brain tumors
- Rare cancers[3]
- Stomach cancer

[1] The definition of adolescents and young adults is derived from the National Cancer Institute (NCI) (https://www.cancer.gov/types/aya). Research should be targeted toward children (ages 0-14 years), adolescents (ages 15-24 years), and/or young adults (ages 25-39 years).
[2] As derived from the *NCI 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.
[3] Rare cancer is defined by the NCI as a cancer that occurs in fewer than 15 out of 100,000 people each year (https://www.cancer.gov/publications/dictionaries/cancer-terms/def/791790).

New for FY19: Studies involving melanoma (including rare subtypes of melanoma) should apply to the new FY19 Melanoma Research Program. Studies involving other skin cancers will be accepted by the PRCRP under an appropriate FY19 PRCRP Topic Area (i.e., immunotherapy).

II.A.2. FY19 PRCRP Military Health Focus Areas

In addition to addressing at least one of the required FY19 PRCRP Topic Areas, applications for the FY19 PRCRP TTSA ***must*** also address at least one of the FY19 PRCRP Military Health Focus Areas. Relevance to military in medical research focuses on critical issues or gaps in biomedical knowledge that may affect the health and well-being of the military.

It is central to the vision and mission of the PRCRP that applications address how the proposed research is related to military health, mission readiness, and the cancer health needs of both deployed and non-deployed military personnel, their dependents, Veterans, and other military beneficiaries (i.e. family members of retirees). The FY19 PRCRP requires all applications address at least one of Military Health Focus Areas listed below:

- ***Environmental/exposure risk factors associated with cancer***
- ***Gaps in cancer prevention, early detection/diagnosis, prognosis, treatment, and/or survivorship that may impact mission readiness and the health and well-being of military members, Veterans, their beneficiaries, and the general public***

Environmental risk factors should be relevant to activities specific to the military such as deployments that may lead to exposures to potential carcinogens (ionizing radiation, chemicals, infectious agents, etc.). For more information on military-related exposures and risk factors for cancer, applicants should refer to Exposure Related Health Concerns at https://www.publichealth.va.gov/exposures/health-concerns.asp or to the PRCRP website (https://cdmrp.army.mil/prcrp/default).

Examples of impact on mission readiness may include but are not limited to: improvements in survival while minimizing late effects that would allow an active duty Service member to return to full duty; treatments that minimize a cancer patient's (either Service member or their family member) time in the hospital thus maximizing the time the Service member is on duty; minimizing cancer relapse for Service members or their families (in the event of a family member's relapse the active duty Service member is called home regardless of deployment status); and improvements in cancer detection that would lead to the earlier diagnosis thus allowing for treatment of Service member and early return to duty. More information on mission readiness can be found at https://cdmrp.army.mil/prcrp/pbks/prcrppbk2017.pdf.

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 FY19 PRCRP Translational Team Science Award (TTSA) supports ***hypothesis-driven*** translational studies. These studies should be associated with a clinical trial. The proposed project should focus on research for the next-phase clinical trial or future clinical application. The TTSA is intended to support advanced translational studies that are based on results from clinical investigations. ***While funding for clinical trials is allowed, the TTSA is intended to support multi-investigator, multidisciplinary teams to perform clinical research studies and not only to fund a clinical trial.*** Research projects funded by the TTSA should address critical knowledge gaps in clinical outcomes, validate key research results, expand upon potentially game-changing results, or investigate novel clinical findings.

New for FY19: The FY19 PRCRP TTSA Areas of Emphasis (strongly encouraged but not required):

- Interventions to improve quality of life for cancer patients and/or survivors
- Cancer prevention or early detection
- Understanding metastatic disease to improve outcomes

Applications proposing a study not within the scope of the FY19 PRCRP TTSA Areas of Emphasis must demonstrate that the research proposed once translated to the clinic will have lasting impact in the research area studied.

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 FY19 PRCRP Topic Areas.*** At least one military or VA investigator is ***strongly*** 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, civilian DoD investigators, 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 "Relevance to Military Health" 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 be based on clinical trials. 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 translational results, or investigate novel findings.

- **Relevance to Military Health:** ***The proposed research must address at least one of the FY19 PRCRP Military Health Focus Areas.*** The proposed research must be relevant to active duty Service members, Veterans, and other military beneficiaries. For more information, review the following websites: PRCRP (https://cdmrp.army.mil/prcrp/default), PRCRP Report to Congress (https://cdmrp.army.mil/prcrp/reports/reports), Military Health System (MHS) (https://www.health.mil/), and VA (https://www.va.gov/oro/).

- **Impact:** The proposed research should have the potential to have a significant impact on cancer research and/or patient care and the potential to accelerate the movement of promising ideas (in prevention, detection, diagnosis, prognosis, treatment, and/or survivorship) into clinical applications for at least one of the FY19 PRCRP Topic Areas.

- **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.

Collaborations with a military/VA investigator are strongly 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
https://www.wpafb.af.mil/afrl

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

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

Defense Technical Information Center
https://discover.dtic.mil/

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

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/sites/nmcphc/Pages/Home.aspx

Office of Naval Research
https://www.onr.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
https://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
https://www.arl.army.mil

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

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

Walter Reed Army Institute of Research
https://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 (NCI) Cancer Therapy Evaluation Program (CTEP). Detailed information on the activities of the CTEP can be found at https://ctep.cancer.gov/default.htm.

A Congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY19 PRCRP priorities.

The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.

The anticipated direct costs budgeted for the entire period of performance for an FY19 PRCRP TTSA award will not exceed **$1,500,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The CDMRP expects to allot approximately $19.2M to fund approximately 8 Translational Team Science Award applications. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

Awards will be made no later than September 30, 2020. For additional information refer to Section II.F.1, Federal Award Notices.

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 the DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

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) and the award will identify the specific substantial involvement. 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.

The 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.b.ii, Applications Components for the Partnering PI(s); 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 PI will be named to an individual award within the recipient organization.

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

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***. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. 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 as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Applications that involve recruitment of human subjects must indicate the quarterly enrollment targets across all sites in Attachment 5: Statement of Work (SOW). Successful applicants will work with USAMRAA to establish milestones for human subjects recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones. 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.

New FY19 definition: A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Funded trials are required to post a copy of the IRB approved informed consent form used to enroll subjects on a publicly available Federal website in accordance with Federal requirements described in 32 CFR 219).

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 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 award date or if the documented status of the IND or IDE has not been obtained within 6 months of the award date.

Use of DoD or VA Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs/co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information.

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 the General Application Instructions, Appendix 1, for additional information.

Collaborative and Integrative Biology Data and Project Support Platform: SysBioCube (https://sysbiocube-abcc.ncifcrf.gov/) is the USAMRMC biomedical research data access, sharing, management and analysis platform. Its operation is directed by the USAMRMC Systems Biology Collaboration Center (SBCC). The SysBioCube is developed and hosted at Frederick National Laboratory for Cancer Research sponsored by the NCI/National Institutes of Health (NIH). The SysBioCube is a central web portal for data harmonization, integration, and mining. The features and tools within the SysBioCube help ensure the integrity of project data for longevity, as well as offer project management support, particularly for collaborative, multi-site studies. Overall, the system is designed to enhance research projects being conducted by the military-supported biomedical research community, both intra- and extramurally. Interested researchers should inquire at sysbiocube@mail.nih.gov. Use of the SysBioCube must be called out in the research application, as there is a fee associated with its use.

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.

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 academic institutions, biotechnology companies, foundations, other Federal Government organization other than the DoD, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.

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

II.C.1.b. Principal Investigator

The investigator named as the Initiating PI on the application must be at or above the level of Assistant Professor or equivalent.

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

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

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 https://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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.

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 offered by the FY19 PRCRP is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission: An application submitted by an organization to Grants.gov.

Intramural DoD Submission: An application submitted by a DoD organization to eBRAP.

II.D.1. Address to Request Application Package

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.

Extramural Submissions:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submissions:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted 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/).

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

Extramural Organization Submissions: Full applications from extramural organizations must be submitted through Grants.gov Workspace. 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. Applications from

extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

Intramural DoD Organization Submissions: 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.

For Both Extramural and Intramural Applicants: eBRAP allows 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 full 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 submission 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 the notification 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(s) must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI(s). Applicants are urged to complete these steps as soon as possible. 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. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full application package components to eBRAP.

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay 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 to request a change in designation.

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 applicant organization and associated PIs 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.

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

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**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

  Enter contact information for the Initiating 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 Research & Related 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 Initiating PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the Initiating PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related 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.

  FY19 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.

  The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.

- **Tab 4 – Conflicts of Interest (COIs)**

  List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).

- **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 (two-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 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 findings, and any novel outcomes from a clinical trial. Concisely state the hypothesis, objectives, specific aims, and experimental design. Briefly describe how the preliminary data support the project's rationale and objectives. Describe the clinical research objectives and goals. Describe how the project will leverage information from clinical trials or other clinical data to address knowledge gaps in clinical observations. If applicable, state how the proposed research will address the FY19 PRCRP TTSA Areas of Emphasis in Section II.B. If applicable, describe the

associated clinical trial that would be wholly or partially funded by the FY19 PRCRP TTSA.

- **Translation:** Describe the reciprocal transfer of information between basic and clinical science in developing, implementing, and moving the proposed research and the anticipated outcomes into clinical applications in at least one of the FY19 PRCRP Topic Areas in Section II.A.1. Identify the FY19 PRCRP TTSA Area of Emphasis proposed or other critical cancer issue to be studied.

- **Relevance to Military Health and Impact:** State which of the FY19 PRCRP Military Health 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 well the roles and responsibilities of each partner, including the DoD 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 findings, and any novel outcomes. How well the project's objectives, specific aims, and experimental design are based on preliminary data and derived from a clinical trial. Whether research objectives and goals are described according to the intent of the TTSA (see Section II.B). Whether the project leverages clinical information and addresses knowledge gaps in the resulting outcomes. How well the proposed research will address the FY19 PRCRP TTSA Areas of Emphasis or other critical cancer research area.

- **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 FY19 PRCRP Topic Areas in Section II.A.1.

- **Relevance to Military Health and Impact:** Whether at least one of the FY19 PRCRP Military Health 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, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated 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 notification of invitation has been received by the Initiating PI.

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 (https://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 Each Partnering PI section.

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

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out

webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the ***same version*** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the "Apply For Grants" page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. 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-19-PRCRP-TTSA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-19-PRCRP-TTSA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related 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 Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research &Related Subaward Budget Attachment(s) Form (if applicable)	**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 **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	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. **Note:** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to*** the application submission deadline.	**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 next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.
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 may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***.	After eBRAP has processed the full application, the organizational Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive 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 may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***. Your Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Extramural Submissions	Intramural DoD Submissions
assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	

Both Extramural and Intramural Organizations: Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Research & Related Budget form 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. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. ***Note: All associated applications (Initiating PI's and each Partnering PI's) 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 Research & Related 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 the General Application Instructions, Appendix 4.

  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 have 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.***

  - **Research Background and Objectives:** Present the hypothesis and reasoning behind the proposed research. Describe the clinical research objectives and goals. Describe the clinical trial to be leveraged. Identify the critical knowledge gaps, key research, and potentially transformative findings, or novel outcomes from the clinical trial. Describe how the previous clinical research or trial outcomes relate and support the objectives and goals of the proposed study. State how the proposed research will address the FY19 PRCRP TTSA Areas of Emphasis in Section II.B or other critical cancer research area.

  - **Specific Aims:** Concisely explain the project's specific aims. If this research project is a correlative study to a 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 upon which this project will be based. 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. Describe potential problems and potential pitfalls, and address alternative approaches. Include how the proposed research addresses an important clinical and/or translational question relevant to at least one of the FY19 PRCRP Topic Areas in Section II.A.1 *and* at least one of the FY19 PRCRP Military Health Focus Areas in Section II.A.2. Describe the statistical plan with appropriate power analysis and how it supports the sample size. 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. 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 Initiating PI, Partnering PI(s), 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 10.***

- **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.

  There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative 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 articles 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.

  - Letters of Collaboration: 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.
- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.
- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **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 FY19 PRCRP Topic Area(s) in Section II.A.1 to be addressed by the proposed research. State the FY19 PRCRP Military Health Focus Area(s) in Section II.A.2 to be addressed. Present the ideas and reasoning behind the proposed work. Describe the clinical outcomes upon which the study is founded. Identify the FY19 PRCRP TTSA Areas of Emphasis or other critical cancer research area to be studied.
  - **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.

- **Relevance to Military Health and Impact:** Identify the FY19 PRCRP Military Health 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, detection, diagnosis, prognosis, treatment, and/or survivorship) in at least one of the FY19 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 FY19 PRCRP Topic Area(s) in Section II.A.1 to be addressed by the research project. Identify the FY19 PRCRP TTSA Areas of Emphasis or other critical cancer research area to be study.

  - 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***.

  - In lay persons' terms, 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 FY19 PRCRP Topic Areas?

  - State the FY19 PRCRP Military Health Focus Area(s) in Section II.A.2 to be addressed by the research project. Describe how the proposed research is relevant to active duty Service members, Veterans, and other military beneficiaries.

- **Attachment 5: Statement of Work (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 requirements.
- 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 applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND and IDE applications) 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 [each] Partnering PI 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 partner 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. Describe the regulatory strategy, if applicable. The post-award transition plan should include the components listed below.

- The development and/or commercialization strategy, if applicable.

- The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication. Describe in detail the FDA regulatory strategy, to include considerations for compliance with Good Manufacturing Practice, Good Laboratory Practice, and Good Clinical Practice guidelines, if appropriate.

- 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: Relevance to Military Health Statement (one-page limit): Upload as "MilHealth.pdf".** ***The Relevance to Military Health Statement will be evaluated by the FY19 PRCRP Programmatic Panel during programmatic review only.***

  - State the FY19 PRCRP Topic Area(s) in Section II.A.1 to be addressed in the study.

  - Identify the militarily relevant risk factors associated with the FY19 PRCRP Military Health 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 MHS 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 9: Impact Statement (one-page limit): Upload as "Impact.pdf".** ***The Impact Statement should be written in plain language for lay persons***. State explicitly how the proposed work addresses a critical problem in at least one of the FY19 PRCRP Topic Areas in Section II.A.1.

  - Describe the translational aspects of the proposed research.

  - In lay persons' terms explain the significance of the translational value of the proposed work based on potential clinical and/or translational research outcomes, or current treatment and care options.

- **Attachment 10: 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, and 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, if applicable. 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 11: Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s) (e.g., Human 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 12: 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 13: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 14: DoD Military Budget Form(s), if applicable: Upload as "MFBudget.pdf".** If a military facility (MHS facility, research laboratory, medical 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**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: 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.

Research & Related Senior/Key Person Profile (Expanded): 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.

- Initiating 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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

- Initiating PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

- Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf".

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

Research & Related Budget: 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.

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 have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as 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.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

  - **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 14. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & 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. **Note:** Applicants should 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.8, for detailed information.

Application Components for Each Partnering PI

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 each Partnering PI will be named on 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 each Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

  Attachments:

  - **Attachment 5: Statement of Work (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 each Partnering PI should be noted for each task.

- **Attachment 13: Representations (Extramural Submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 14: DoD Military Budget Form: Upload as "MFBudget.pdf".** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget form under subaward costs.

Research & Related Personal Data: 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.

Research & Related Senior/Key Person Profile (Expanded): 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.

- Partnering 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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

- Partnering PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

- Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf".

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf".

Initiating and Partnering PIs must each submit a budget and justification specific to his/her own portion of the efforts as part of his/her separate Grants.gov application packages. The Research & Related Budget for each Partnering PI 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.6, and for intramural submissions (via eBRAP), refer to General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related 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.7, for detailed information.)

  - **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 14. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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

Applicant organizations and all sub-recipient 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 organization's Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at 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. Pre-application and application submissions are required. 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

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.

Extramural Submission: 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.

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of the 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. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

The maximum period of performance is **4** years.

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.

The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and each Partnering PI's applications will not exceed **$1,500,000**. 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 **$1,500,000** or use an indirect cost rate exceeding each organization's negotiated rate.

A separate award will be made to each PI's organization. If the Initiating PI and the Partnering PI(s) are at the same organization, separate applications must be submitted and separate awards will be made.

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 to present project outcomes from the FY19 PRCRP TTSA.

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). 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 funds 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.

Refer to the General Application Instructions, Section III.A.5, 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.5***.

Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

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 appropriate the rationale, experimental design, and methodology are 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 whether 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 addresses either a FY19 PRCRP TTSA Area of Emphasis, as described in Section II.B, or other critical cancer gap.
    - How well the application acknowledge potential problems and potential pitfalls, and address 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.
    - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- **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 a sound rationale and 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 for the proposed study and the specified FY19 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 an important clinical and/or translational question relevant to at least one of the FY19 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 FY19 PRCRP Topic Areas.
- **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.
  - How the regulatory strategy and the development plan to support the proposed product label, if applicable, are appropriate and well described.
  - 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 anticipated research outcomes to the next level of development 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 **direct** maximum costs are equal to or less than the allowable direct maximum 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 origin of 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 FY19 PRCRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition

- Relevance to FY19 PRCRP Military Health Focus Areas
- Relative Translational potential
- Programmatic relevance to the FY19 PRCRP TTSA Areas of Emphasis or other critical cancer research area
- 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**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA). ***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 https://cdmrp.army.mil/about/2tierRevProcess. A PI Information Paper describing the funding recommendations and review process for the award mechanisms for the PRCRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring 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 and approval 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 and approval 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, as defined in 2 CFR 200.88, 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 organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization 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 (DoDGARs), 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 supported with FY19 funds are anticipated to be made no later than September 30, 2020. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from 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 document.**

Federal Government Organizations: Funding made 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 Manager/Task Area Manager/Comptroller or equivalent Business Official.

After email notification of application review results through 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. PI Changes and Award Transfers

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

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

Unless otherwise restricted changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

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 DoDGARs found in 32 CFR, Chapter I, 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 latest DoD R&D General Terms and Conditions, the USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions 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. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

Quarterly technical progress reports may be required.

In addition to written progress reports, annual Award Charts will be required. For the TTSA mechanism, use the format example "Award Charts," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm).

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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 Representations (see General Application Instructions, Appendix 5, Section B).

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 Versions

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20190218b. The Program Announcement numeric version code will match the General Applications Instructions version code 20190218.

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 FY19 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 FY19 PRCRP Programmatic Panel members can be found at https://cdmrp.army.mil/prcrp/panels/panels19.
- The application fails to conform to this Program Announcement description.

- 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 FY19, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP.
- Applications submitted by an intramural DoD organization if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year (FY19 PRCRP).
- The invited application proposes a different research project than that described in the pre-application.
- All associated (Initiating and Partnering PIs') applications are not submitted by the deadline.
- The applicant fails to demonstrate access to the relevant study population or resources.
- The pre-application or application does not address at least one of the FY19 PRCRP Topic Areas in Section II.A.1.
- The pre-application or application does not address at least one of the FY19 PRCRP Military Health Focus Areas in Section II.A.2.
- The pre-application or application proposes breast, prostate, lung (excluding mesothelioma), kidney, melanoma, or ovarian cancer research.
- The applicant fails to demonstrate access to the relevant study population or resources.

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 Research & Related Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete 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"		
	Relevance to Military Health Statement: Upload as Attachment 8 with file name "MilHealth.pdf"		
	Impact Statement: Upload as Attachment 9 with file name "Impact.pdf"		
	Clinical Strategy Statement: Upload as Attachment 10 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 11 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 12 with file name "Hazardous.pdf" if applicable		
	Representations (Extramural submissions only): Upload as Attachment 13 with file name "MandatoryReps.pdf" if applicable		
	DoD Military Budget Form(s): Upload as Attachment 14 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		
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		
Research & Related Subaward Budget Attachment(s) Form	Complete form as instructed		

APPENDIX 1: ACRONYM LIST

ABTC	Adult Brain Tumor Consortium
ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
BMT CTN	Blood and Marrow Clinical Trials Network
CDC	Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CITN	Cancer Immunotherapy Trials Network
COI	Conflict of Interest
CTEP	Cancer Therapy Evaluation Program
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
ETCTN	Experimental Therapeutics Clinical Trials Network
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
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
NCI	National Cancer Institute
NCTN	National Clinical Trials Network
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PBTC	Pediatric Brain Tumor Consortium
PI	Principal Investigator
PPTC	Pediatric Preclinical Testing Consortium
PRCRP	Peer Reviewed Cancer Research Program
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and Mathematics

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