I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Expansion Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-19-PRMRP-EA

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), March 14, 2019
- **Invitation to Submit an Application:** May 2019
- **Application Submission Deadline:** 11:59 p.m. ET, July 11, 2019
- **End of Application Verification Period:** 5:00 p.m. ET, July 16, 2019
- **Peer Review:** August 2019
- **Programmatic Review:** October/November 2019

This Program Announcement must be read in conjunction with the General Application Instructions, version 20181120. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2019 (FY19) Peer Reviewed Medical Research Program (PRMRP) 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 PRMRP was initiated in 1999 to provide support for military-related health research of exceptional scientific merit. Appropriations for the PRMRP from FY99 through FY18 totaled $2.0 billion (B). The FY19 appropriation is $350 million (M).

The vision of the FY19 PRMRP is to improve the health, care, and well-being of all military Service members, Veterans, and beneficiaries. The PRMRP challenges the scientific and clinical communities to address the FY19 PRMRP Topic Areas with original ideas that foster new directions along the entire spectrum of research and clinical care. The program seeks applications in laboratory, clinical, behavioral, epidemiologic, and other areas of research to advance knowledge in disease etiology, improve prevention, detection, diagnosis, treatment, and quality of life for those affected by a relevant disease or condition, and to develop and validate clinical care or public health guidelines.

II.A.1. FY19 PRMRP Topic Areas

All applications for PRMRP funding must specifically address at least one of the Topic Areas as directed by Congress and have direct relevance to military health. If the proposed research does not specifically address at least one of the FY19 PRMRP Topic Areas, the Government will administratively withdraw the application. The Government reserves the right to reassign the application's Topic Area if submitted under an inappropriate Topic Area. The FY19 PRMRP Topic Areas are listed below.

- Acute Lung Injury
- Antimicrobial Resistance
- Arthritis
- Burn Pit Exposure
- Cardiomyopathy
- Cerebellar Ataxia
- Chronic Migraine and Post-Traumatic Headache
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Dystonia
- Eating Disorders

- Emerging Infectious Diseases
- Epidermolysis Bullosa
- Focal Segmental Glomerulosclerosis
- Frontotemporal Degeneration
- Guillain-Barré Syndrome
- Hemorrhage Control
- Hepatitis B
- Hereditary Angioedema
- Hydrocephalus
- Immunomonitoring of Intestinal Transplants
- Inflammatory Bowel Diseases
- Interstitial Cystitis
- Lung Injury
- Metals Toxicology
- Mitochondrial Disease
- Musculoskeletal Disorders
- Myotonic Dystrophy
- Nanomaterials for Bone Regeneration
- Nutrition Optimization
- Pancreatitis
- Pathogen-Inactivated Blood Products
- Polycystic Kidney Disease
- Post-Traumatic Osteoarthritis
- Pressure Ulcers
- Pulmonary Fibrosis
- Resilience Training
- Respiratory Health
- Rett Syndrome
- Rheumatoid Arthritis
- Scleroderma
- Sleep Disorders
- Spinal Muscular Atrophy
- Tinnitus
- Tissue Regeneration
- Tuberculosis
- Vascular Malformations
- Women's Heart Disease

Applicants should select the FY19 PRMRP Program Announcement most appropriate to the stage of the proposed research. Areas of Encouragement related to the FY19 PRMRP Topic Areas have been identified by the Department of Defense (DoD), the Department of Veterans Affairs (VA), and other relevant stakeholders (Appendix 2). Applicants are urged to read and consider these Areas of Encouragement before preparing their applications. ***The information provided is not exhaustive, and applicants are not restricted to submitting applications that address an Area of Encouragement on this list.***

II.B. Award Information

The FY19 PRMRP Expansion Award is designed to support the continued investigation and further development of highly impactful research projects that were previously funded through the following previous PRMRP funding opportunities:

- PRMRP FY12-FY16 Discovery Award
- PRMRP FY12-FY15 Investigator-Initiated Research Award
- PRMRP FY12-FY15 Technology/Therapeutic Development Award

All Expansion Award applications must align with at least one of the FY19 PRMRP Congressionally specified Topic Areas, regardless of the Topic Area(s) of the original project.

Research proposed under this award mechanism may be at different stages of idea and research development. Four different funding levels, based on the scope of the research, are available under this Program Announcement. The applicant must select the funding level that is most appropriate for the research proposed.

- **Funding Level 1:** Research that is supported by preliminary data but is still at early stages of translational and clinical development. It is anticipated that successful projects previously funded through the PRMRP Discovery Award will be most appropriate for continuation under Funding Level 1. Anticipated direct costs of Funding Level 1 will not exceed $500,000.

- **Funding Level 2:** Research that is supported by significant preliminary data and has the potential for translation into clinical application. It is anticipated that successful projects previously funded through the PRMRP Investigator-Initiated Research Award, or successful Discovery Award projects accompanied by clear justification for this level of funding, will be most appropriate for continuation under Funding Level 2. Anticipated direct costs of Funding Level 2 will not exceed $1.2M.

- **Funding Level 3:** Product-oriented research that is in the final stages of preclinical development with potential for near-term clinical development. It is anticipated that successful projects previously funded through the PRMRP Technology/Therapeutic Development Award NOT ready for clinical trial research, or successful product-oriented Investigator-Initiated Research Award projects accompanied by clear justification, will be most appropriate for continuation under Funding Level 3. Anticipated direct costs of Funding Level 3 will not exceed $3.0M.

- **Funding Level 4:** Product-oriented research that includes either 1) some preclinical work and an early phase (pilot, Phase I, Phase II, or equivalent) clinical trial or 2) an early phase (pilot, Phase I, Phase II, or equivalent) clinical trial. It is anticipated that successful projects previously funded through the PRMRP Technology/Therapeutic Development Award ready for clinical trial will be most appropriate for continuation under Funding Level 4. Anticipated direct costs of Funding Level 4 will not exceed $5.0M.

Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

All FY19 PRMRP Expansion Award applications must include an Outcomes Statement (Attachment 5), which is a summary of the research funded through the original PRMRP award and a description of the research accomplishments and outcomes from that award. Applications should explain how these accomplishments and outcomes relate to the proposed research. Applications should also describe how either the expansion of the original research idea or the new research idea based on the original project will impact a central critical problem or question in the field of research and/or patient care in the FY19 PRMRP Topic Area(s) addressed. **Preliminary data are required**. Each Principal Investigator (PI) is eligible to submit one Expansion Award application per qualifying previous PRMRP award received. ***Clinical trials are allowed only under an Expansion Award at Funding Level 4.***

The CDMRP expects to allot approximately $32M to fund approximately 6 Expansion 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.

Relevance to Military Health: Relevance to the healthcare needs of military Service members, Veterans, military beneficiaries, and/or the American public is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate relevance to military health:

- Explanation of how the project addresses an aspect of the target disease/condition that has direct relevance to the health of military Service members, Veterans, or other Military Health System beneficiaries

- Explanation of how the project addresses an aspect of the target disease/condition/technology that has relevance or is unique to the military or family readiness of Service members

- Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need

- Use of military or Veteran populations or datasets in the proposed research, if appropriate to the proposed research project

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD or VA investigators is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration within the FY19 PRMRP Topic Areas can be found in Appendix 3.

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 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 4: 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.

A clinical trial is defined as a prospective accrual of human subjects in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

The term "human subjects" is used in this Program Announcement to refer to individuals who will be recruited for or who will participate in the proposed clinical trial. For more information, a Human Subject Resource Document is provided at https://ebrap.org/eBRAP/public/Program.htm.

Expansion Award applications that include a clinical trial (Funding Level 4) have additional application and review requirements. For more information, see Section II.D.2, Content and Form of the Application Submission and Section II.E.1, Criteria.

- ***For Funding Level 4 applications without preclinical research:***
    - If the application proposes a clinical trial, and the proposed 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, then an Investigational New Drug (IND) application to the FDA that meets all requirements under the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312) ***may be required and should be submitted to the FDA by the application submission deadline.***

- If the application proposes a clinical trial and 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 to the FDA by the application submission deadline, or that the device is exempt or qualifies for an abbreviated IDE, is required.

- If the clinical trial of an investigational product will be conducted at international sites, evidence that an application to the relevant national regulatory agency of the host country(ies) has been submitted by the application submission deadline is required.

- If an IND or IDE is required, it should be specific for the product (i.e. the product should not represent a derivative or alternate version of the investigational agent described in the FDA application) and indication to be tested in the proposed clinical trial. Documentation that the IND or IDE application has been submitted to the FDA or that the clinical trial does not require FDA regulation is required at the time of application submission; see Attachment 9, Transition Plan and Regulatory Strategy, for more information.

- ***For Funding Level 4 applications with preclinical research:***

  - If an IND or IDE will be required to support an Expansion Award application that includes some preclinical work to be completed prior to an early phase (pilot, Phase I, Phase II, or equivalent) clinical trial, then a proposed submission date of the IND or IDE application to the FDA should be included in the application (including in the Statement of Work, see Attachment 4). A detailed plan describing how FDA requirements and filings will be met and completed is required; see Attachment 9, Transition Plan and Regulatory Strategy, for more information.

  - If the clinical trial will be conducted at international sites, the proposed submission date to the relevant national regulatory agency is required.

The Government reserves the right to withdraw funding if an IND or IDE and/or international regulatory application is necessary for Funding Level 4 clinical trial without preclinical research, but has not been submitted to the FDA prior to the application submission deadline.

The following are important aspects of submissions proposing clinical trials:

- The proposed intervention(s) to be tested should offer significant potential impact for individuals affected by the specified disease(s)/condition(s).

- Inclusion of preliminary data relevant to the proposed clinical trial is required.

- The proposed clinical trial must be based on sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.

- The application should describe the planned indication for the product label, if appropriate, and include an outline of the product development plan required to support that indication.

- The application should demonstrate availability of, and access to, a suitable patient population that will support a meaningful outcome for the study. The PI should discuss how accrual goals will be achieved and how standards of care may impact the study population.

- The application should demonstrate documented availability of and access to the drug/ compound, device, and/or other materials needed, as appropriate, for the proposed duration of the study. The quality and stability of the product should be documented and commensurate with current FDA manufacturing standards applicable to the type and phase of product being developed (i.e., Quality System Regulation, Good Manufacturing Practice [GMP]).

- The application should demonstrate the study team has experience interacting with the FDA to include previous FDA submissions, if applicable.

- The proposed clinical trial design should include clearly defined objectives and appropriate endpoints/outcome measures, and comply with current Good Clinical Practice (GCP) guidelines.

- The application should include a clearly articulated statistical analysis plan, appropriate statistical expertise on the research team, and a power analysis reflecting sample size projections that will answer the objectives of the study.

- The application should include a clearly articulated data management plan and use of an appropriate database to safeguard and maintain the integrity of the data. If FDA regulated, the trial must use a 21 CFR 11-compliant database and appropriate data standards. For more on data standards, see https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM511237.pdf.

- The application should include a clearly articulated safety management plan outlining how safety pharmacovigilance will be conducted, as applicable.

- The application should include a clearly articulated clinical monitoring plan outlining how the study will be monitored for GCP compliance.

- The application should include a study coordinator(s), who will guide the clinical protocol through the local IRB of record and other Federal agency regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual.

- The application should include a Transition Plan (including potential funding and resources, see Attachment 9) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of the award.

- The application should clearly demonstrate strong institutional support and, if applicable, a commitment to serve as the FDA regulatory sponsor, ensuring all sponsor responsibilities described in 21 CFR 312, Subpart D, are fulfilled.

- Funded clinical trial studies are required to file the study in the National Institutes of Health (NIH) clinical trials registry, www.clinicaltrials.gov. Refer to the General Application Instructions, Appendix 1, Section C, for further details.

Multi-Institutional Clinical Trials: If the proposed clinical trial is multi-institutional, plans for the multi-institutional structure governing the research protocol(s) should be outlined in Attachment 11: Study Personnel and Organization. The lead organization responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements. A single IRB/EC pathway is strongly recommended whenever possible. The master protocol and consent form must be reviewed by HRPO prior to distribution to the additional sites for IRB/EC review. Communication and data transfer among the collaborating institutions, as well as how specimens and/or imaging products obtained during the study will be handled, should be included in the appropriate sections of the application. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional clinical trials.

Research Involving Animals: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research. *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf.

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.

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

Only PIs funded by a PRMRP FY12-FY16 Discovery Award, PRMRP FY12-FY15 Investigator-Initiated Research Award, or a PRMRP FY12-FY15 Technology/Therapeutic Development Award are eligible to be named as a PI on the application. For the FY12-FY15 PRMRP Investigator-Initiated Research Awardees under the Partnering PI Option, either or both PIs (Initiating or Partnering) may be named by the organization as the PI on the application.

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

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

Each PI is eligible to be named as a PI on one application per PRMRP FY12-FY16 Discovery Award, PRMRP FY12-FY15 Investigator-Initiated Research Award, or PRMRP FY12-FY15 Technology/Therapeutic Development Award received.

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

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

II.D. Application and Submission Information

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the FY19 PRMRP is prohibited and will result in administrative withdrawal of the duplicative application(s). As an exception, applicants may submit the research project described in their Expansion Award application as part of an application to the FY19 PRMRP Focused Program Award (Funding Opportunity Number: W81XWH-19-PRMRP-FPA); however, accepting multiple awards to support the same project will not be allowed.

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.

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 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.

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.

  Select the Funding Level that is most appropriate for the proposed research project.

  Select the FY19 PRMRP Topic Area addressed by the proposed research. If the proposed research project is aligned with more than one FY19 PRMRP Topic Area, select the Topic Area of highest relevance as the required first choice.

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 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 PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds

to Block 5 on the Grants.gov SF424 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 PRMRP 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.

- **Tab 4 – Conflicts of Interest**

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

- **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 (six-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 be described using the FY19 PRMRP Expansion Award Preproposal outline below:

    - Describe the research and accomplishments of the original PRMRP award that is the basis for the proposed follow-on effort. Include the following information:

      - Award Mechanism
      - Title of Project/PI/Institution/log number (i.e., PR######)
      - Summarize the goal and aims of the original PRMRP research.

- Describe the accomplishments and any products (e.g., drug, device, biologic, animal model, technology, etc.) from this previous PRMRP award.
- Describe any challenges associated with completing the prior PRMRP research award, and how they were resolved.
- Provide a list of research outcomes (e.g., publications, patents, presentations, development of resources) resulting from this prior award.

– Describe the proposed follow-on research effort for consideration under the FY19 PRMRP Expansion Award. Include the following information:

- Title of Project
- List Key Personnel, including the PI, and roles in the proposed research.
- Describe how the proposed new research effort relates to at least one of the FY19 PRMRP Topic Areas.
- Describe the proposed new research effort with concisely stated objectives, specific aims, and references.
- Explain how the accomplishments and outcomes from the original funded research relate to this proposed follow-on effort, and if the proposed research expands on or is a new idea generated from the prior work.
- Describe any potential challenges and how they might be resolved.
- Describe the expected outcome(s) and the impact on the field of research or on patient/survivor care. Outline how the project is relevant to the healthcare needs of military Service members, Veterans, and/or 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 PRMRP, pre-applications will be screened based on the following criteria:

  - How the proposed research is an expansion of or a new idea based on the research progress and outcomes from the original PRMRP-funded project.
  - To what extent the original PRMRP-funded project was successful.
  - Whether the potential immediate and long-range outcome(s) of the proposed research, if successful, will impact a central critical problem or question in the field of research and/or patient care in the FY19 PRMRP Topic Area(s) addressed.
  - To what degree the project is relevant to military health, the healthcare needs of military Service members, Veterans, and/or 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.

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.

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-PRMRP-EA 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-PRMRP-EA 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 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	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Extramural Submissions	Intramural DoD Submissions
automatically 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 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 (page limit varies by funding level; see below for 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.

Page Limit: Page limits for the Project Narrative are correlated with the application's funding level:

- **Funding Level 1:** 8-page limit
- **Funding Level 2:** 12-page limit
- **Funding Level 3:** 18-page limit
- **Funding Level 4:** 25-page limit

Describe the proposed project in detail using the outline below.

- **Background:** Describe how the proposed research project addresses one or more of the FY19 PRMRP Topic Areas. Present the ideas and reasoning on which the proposed work is based, with appropriate emphasis on the previous PRMRP-funded project. Cite relevant literature. Describe previous experience most pertinent to the project. Include relevant preliminary data; these data may be unpublished or from the published literature.
- **Hypothesis/Objective:** State the hypothesis to be tested.
- **Specific Aims:** Concisely explain the project's specific aims and the objective(s) to be reached. These aims should agree with the primary aims and associated tasks described in the Statement of Work. If the proposed work is part of a larger study, present only aims that this DoD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines (http://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf). If human subjects or human biological samples will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples. Describe the availability of the proposed study population and past successes in recruiting similar populations. If active duty military, military families, and/or Veteran population(s) or datasets will be used in the proposed research project, describe the feasibility of accessing the population(s)/dataset(s).
- **Statistical Plan:** Clearly describe a statistical plan appropriate to the type of study; provide the rationale for the statistical methodology. Define the number of samples

and/or subjects (animal and/or human) to be used, and include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

In addition to the above, for applications requesting Funding Level 4, i.e., product-oriented research that must include an early phase (pilot, Phase I, Phase II, or equivalent) clinical trial, the following should be included:

- **Clinical Trial:** Provide detailed plans for initiating and conducting the clinical trial during the course of this award. Describe the type of clinical trial to be performed (e.g., treatment, prevention, diagnostic, etc.), the phase of trial and/or class of device (as appropriate), and the study model (e.g., single group, parallel, crossover, etc.).

  - Identify the intervention to be tested and describe the projected results.

  - Define the primary and any secondary or interim endpoints/outcome measures, outline why they were chosen, and describe how and when they will be measured. Include a description of appropriate controls. Outline the timing and procedures planned during the follow-up period.

  - Describe the study population and the inclusion and exclusion criteria that will be used.

  - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).

  - Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures). Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).

  - Outline whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.

  - If using psychometric measures, describe their reliability and validity.

  - Describe potential problem areas and discuss alternative methods/approaches that may be employed to overcome them. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.

  - Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation

study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- **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 (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- Letter of Commitment **(Funding Level 4 only)**: If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating availability of the product for the duration of the trial, support for the proposed phase of research, and support for the indication to be tested.

- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (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): If the proposed research plan involves access to active duty military patient populations or resources, the PI is responsible for demonstrating such access. 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 and Lay Abstracts (two-page limit): Upload as "Abs.pdf".** Start each abstract on a new page. The technical and lay abstracts are 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 Abstract: Programmatic reviewers typically do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

  - **Background:** Present the ideas and rationale behind the proposed clinical research.

- **Relevance to Topic Area(s):** State the relevance of the project to at least one FY19 PRMRP Topic Area. If applicable, describe how the proposed research project addresses an FY19 PRMRP Area of Encouragement (Appendix 2).

- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.

- **Specific Aims:** State the specific aims of the study.

- **Study Design:** Briefly describe the study design, including appropriate controls.

- **Clinical Impact:** Briefly describe how the proposed project will have an impact on research and patient care in the specified disease(s)/condition(s).

- **Relevance to Military Health:** Describe the study's relevance to the healthcare needs of military Service members, Veterans, and/or beneficiaries.

Lay Abstract: Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.***

- Clearly describe the objectives and rationale for the proposed study in a manner readily understood by readers without a background in science or medicine.

- State the FY19 PRMRP Topic Area(s) addressed by the proposed research project. If applicable, describe how the proposed research project addresses an FY19 PRMRP Area of Encouragement (Appendix 2).

- Describe the ultimate applicability and impact of the research.

  - What types of patients will it help, and how will it help them?

  - What are the potential clinical applications and benefits?

- **Attachment 4: 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 Expansion Award 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.

- If applicable, indicate timelines required for regulatory approvals relevant to human or animal subjects research (e.g., IRB, IACUC, ORP, IND and IDE applications) by the FDA or other Government agency.

- **Attachment 5: Outcomes Statement (two-page limit): Upload as "Outcomes.pdf".** Provide a summary of the research funded through the original PRMRP FY12-FY16 Discovery Award, PRMRP FY12-FY15 Investigator-Initiated Research Award, or PRMRP FY12-FY15 Technology/Therapeutic Development Award. Describe the research accomplishments and research outcomes (publications, patents, etc.) of the original PRMRP-funded award, and explain how they relate to the proposed research project.

- **Attachment 6: Impact Statement (two-page limit): Upload as "Impact.pdf".** Explain why the proposed research project is important and relevant to understanding the cause or progression of the disease or condition, or to developing improvements in prevention, detection, diagnosis, treatment, patient care, or quality of life in the FY19 PRMRP Topic Area(s) addressed. Describe how the study will address a central critical problem or question in the relevant Topic Area(s). If applicable, describe how the project addresses an FY19 PRMRP Area of Encouragement (Appendix 2).

  - ***Describe the short-term impact:*** Detail the anticipated outcomes or products that will be directly attributed to the results of the proposed research.

  - ***Describe the long-term impact:*** Explain the anticipated long-term gains from this research. Compare to the information known/products currently available, if applicable. Explain the long-range vision for how the research will impact the field of study and/or clinical care.

- **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as "MilRel.pdf".** Describe how the proposed study is responsive to the healthcare needs of military Service members, Veterans, and/or beneficiaries. Provide information about the incidence and/or prevalence of the disease or condition in the general population as well as in military Service members, Veterans, and/or beneficiaries.

  If active duty military, military families, and/or Veteran population(s) or datasets will be used in the proposed research project, describe the population(s)/dataset(s) and the appropriateness of the population(s)/dataset(s) for the proposed study. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service members, Veterans, and/or beneficiaries).

Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.

- **Attachment 8: Intervention (no page limit):** ***Only applicable for applications submitted to Funding Level 4.*** **Upload as "Intervention.pdf".** The Intervention attachment should include the components listed below:

  - **Description of the Intervention:** Identify the intervention to be tested and describe the particular outcomes. As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the clinical trial.

    Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.

  - **Study Procedures:** Describe the interaction with the human subject to include the study intervention that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Clearly delineate research procedures from routine clinical procedures. Discuss how compliance with current Good Laboratory Practice (GLP), GMP, and other regulatory considerations will be established, monitored, and maintained, as applicable.

  - **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for current ICH E6 (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) GCP compliance, by an independent clinical trial monitor (or clinical research associate). The clinical monitoring plan should describe the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the Sponsor and PI, and how they will be corrected and prevented by the clinical trial site/PI.

- **Attachment 9: Transition Plan and Regulatory Strategy (no-page limit): Upload as "TransStrat.pdf".** ***Only applicable for applications submitted to Funding Levels 3 and 4.***

  <u>Transition Plan</u>: ***Only applicable for applications submitted to Funding Levels 3 and 4.*** Describe/discuss the methods and strategies proposed to move the anticipated

research outcomes or, if applicable, intervention, to the next phase of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The post-award transition plan should include the components listed below.

- Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.

- For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. 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.

- Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines.

- A brief schedule and milestones for transitioning the intervention to the next phase of development (i.e., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/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.

- A risk analysis for cost, schedule, manufacturability, and sustainability.

Regulatory Strategy: ***Only applicable for applications submitted to Funding Level 4.*** Describe the regulatory strategy using the following outline and provide supporting documentation as applicable prior to the application submission deadline.

- State the product/intervention name.

For products/interventions that do not require regulation by the FDA or an international regulatory agency:

- Explain why the product/intervention is exempt from FDA oversight. Provide confirmation that the trial does not require regulation by the FDA in writing from the IRB of record or the FDA. If the clinical trial will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements. No further information for this Attachment is required.

For products that require regulation by the FDA and/or an international regulatory agency:

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the U.S.

- If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.

- If an IND or IDE is required, it should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. If an IND or IDE application has already been submitted to the FDA, provide the date of submission, the application number, and a copy of the FDA letter acknowledging the submission. ***Note: Funding Level 4 applications without preclinical research are required to submit IND/IDE applications (if applicable) to the FDA by the FY19 PRMRP Expansion Award application submission deadline.*** If there are any existing cross-references in place, provide the application number(s) and associated sponsor(s). Provide an explanation of the status of the application (e.g., statement that the FDA did not raise concerns, past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, on partial clinical hold). If the IND or IDE application has been placed on clinical hold or partial hold, explain the conditions that must be met for release of the hold. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.

- If the proposed project involves some preclinical research prior to initiation of the clinical trial, provide a detailed timeline with appropriate milestones for IND or IDE

application preparation and submission. Provide a summary of previous meetings with the FDA on the development of this product, if applicable. A copy of the Agency meeting minutes should be included if available.

- If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.

- If an active IND or IDE for the investigational product is in effect, but an amendment is needed to include the proposed trial, describe the type and nature of the amendment(s) and the timeline for submission. Indicate whether the amendment increases the risk of the intervention.

- If the clinical trial will be conducted at an international site(s), provide equivalent information and supporting documentation relevant to the product/intervention and regulatory approval in the host country(ies). For Funding Level 4 proposals without preclinical research, applications to an international regulatory approval agency, if applicable, ***must be submitted by the FY19 PRMRP Expansion Award application deadline.***

- Provide a current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing, etc.), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support Phase I testing, etc.), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

- **Attachment 10: Human Subject Recruitment and Safety Procedures (no page limit):** ***Only applicable for applications submitted to Funding Level 4.*** **Upload as "HumSubProc.pdf".** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts that will be made to achieve accrual goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. ***For clinical trials proposing to include military personnel, refer to the General Application Instructions, Appendix 1, for more information.***

- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

  Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare provider identification).

  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.

  - If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.

  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.

  - ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***

  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.

  - Include information regarding the timing and location of the consent process.

  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.

  - Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.

- Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.

- Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. **Note:** In compliance with 10 USC 980 (https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf), the PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial. If applicable, refer to the General Application Instructions, Appendix 1, for more information.

- ***Assent.*** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

– **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. ***Note:*** Some screening procedures may require a separate consent or a two-stage consent process.

– **Risks/Benefits Assessment:**

- **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

- **Risk management and emergency response:**

  - Describe how safety surveillance and reporting to the IRB and FDA (if applicable) will be managed and conducted.

  - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity-grading scales or other predetermined alert values.

- ❖ Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.

- ❖ Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).

- ❖ Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.

- ❖ If the IRB determines that a trial presents greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consistent with the nature of risk(s) identified within the research protocol. If applicable, refer to the General Application Instructions, Appendix 1, Section B (Research Monitor Requirement) for more information on study reporting authorities and responsibilities of the research monitor.

- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **Attachment 11: Study Personnel and Organization (no page limit):** ***Only applicable for applications submitted to Funding Level 4.*** **Start each document on a new page. Combine into one document and upload as "Personnel.pdf".** The Study Personnel and Organization attachment should include the components listed below.

  - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person's position on the project. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate. Identify and provide justification for the inclusion of international sites, as appropriate. If applicable, identify the FDA regulatory sponsor and any external consultants or other experts who will assist with FDA applications. While there is no specified format for this information, a table(s) or diagram is recommended. **Note:** This item may be made available for programmatic review.

  - **Study Personnel Description:** Briefly describe the roles of the individuals listed in the organizational chart on the project. Describe relevant experience and qualifications that demonstrate appropriate expertise for the given role, including

previous interactions with the FDA, if applicable. An external research monitor (if applicable) and study coordinator(s) should be included.

- **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is multi-institutional, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead organization; include a single IRB/EC pathway whenever possible. If applicable, describe how communication and data transfer between the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared.

- **Attachment 12: Data Management (no page limit):** ***Only applicable for applications submitted to Funding Level 4*****. Upload as "Data_Manage.pdf".** The Data Management attachment should include the components listed below.

  - **Data Management:** Describe all methods used for data collection to include the following:

    - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.

    - **Confidentiality:**

      - Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.

      - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DoD are eligible to review study records.

      - Address requirements for reporting sensitive information to state or local authorities.

  - **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For FDA-regulated studies, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) are required.

- **Data reporting:** 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.

- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.

- **Laboratory Evaluations:**

  - **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.

  - **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).

  - **Storage:** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.

  - **Laboratories performing evaluations and special precautions:** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **Attachment 13: Surveys, Questionnaires, and Other Data Collection Instruments:** ***Only applicable for applications submitted to Funding Level 4, and only if applicable.*** **Upload as "Surveys.pdf".** The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.

- **Attachment 14: 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 15: DoD Military Budget Form(s), if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System 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 & Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.8, 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.

  - 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.

  - 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.

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 15. (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.

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 requested funding level should be based on the scope of the research proposed.

Funding Level 1:

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **$500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$500,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Funding Level 2:

- The maximum period of performance is **3** years.

- The anticipated direct costs budgeted for the entire period of performance will not exceed **$1.2M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$1.2M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Funding Level 3:

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

- The anticipated direct costs budgeted for the entire period of performance will not exceed **$3.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$3.0M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Funding Level 4:

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

- The anticipated direct costs budgeted for the entire period of performance will not exceed **$5.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$5.0M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

- For Funding Level 4 in which some preclinical work is proposed in addition to the clinical trial, the clinical trial will be funded as an option.

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 years stated above.

For this award mechanism, direct costs must be requested for:

- **Funding Levels 3 and 4 only:** Travel costs for the PI to present project information or disseminate project results at a Milestone Meeting during the period of performance in year 3 should be requested. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

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

- Salary

- Research supplies

- Equipment
- Research-related subject costs
- Clinical research costs (clinical trials allowed only under Funding Level 4)
- Support for multidisciplinary collaborations, including travel
- Travel costs for the PI to disseminate project results at one DoD-supported meeting to be specified by the program office during award negotiations (e.g., the Military Health System Research Symposium)
- Travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meeting is to present project information or disseminate project results.

Awards made to extramural organizations will consist solely of assistance agreements (grants and/or 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**:

Scored review criteria for applications submitted to <u>Funding Levels 1 and 2, which are listed in decreasing order of importance</u>:

- **Research Strategy and Feasibility**
    - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, supporting data, and logical reasoning.
    - How well the hypothesis, specific aims, and objective(s) are developed.
    - How well the experimental design, methods, data collection procedures, and analyses are developed and support completion of the aims.
    - If applicable, to what degree the statistical plan and power analysis are appropriate for the proposed project.
    - If animal studies are included, how well they are designed to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.
    - If applicable, how well the application provides evidence of availability of and access to the necessary study populations and/or resources.
    - How well potential problems are identified and alternative approaches are addressed.
    - Whether the research can be completed within the proposed period of performance.
- **Impact**
    - To what extent the project impacts a central critical problem or question in at least one FY19 PRMRP Topic Area.
    - If applicable, how well the proposed research project addresses one or more of the FY19 PRMRP Areas of Encouragement.
    - To what degree the proposed research project, if successful, will make important scientific advances in the relevant field of research.
    - To what degree the proposed project could, if successful, make a significant impact on the lives of the relevant patient population(s) in the short term and/or long term.
- **Personnel**
    - How well the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
    - Whether the levels of effort by the PI and other key personnel are appropriate to ensure the successful conduct of the project.

- How well each PI's record(s) of accomplishment demonstrates his/her ability to accomplish the proposed work.

Scored review criteria for applications submitted to <u>Funding Level 3, which are listed in decreasing order of importance</u>:

- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, supporting data, and logical reasoning.
  - To what extent the anticipated outcomes will support the translation of promising preclinical findings into a product for clinical application.
  - How well the hypothesis or objective(s) and specific aims are developed.
  - How well the experimental design, methods, data collection procedures, and analyses are developed and support completion of the aims.
  - The degree to which the expected outcomes are specific and measurable.
  - If applicable, to what degree the statistical plan and power analysis are appropriate for the proposed project.
  - If applicable, the degree to which the plan to study patient populations is appropriate and feasible and whether the application provides evidence of availability of and access to the necessary study populations and/or resources.
  - How well potential problems are identified and alternative approaches are addressed.
  - How well the study (or studies) is designed to achieve the objectives, including the choice of model, if applicable, and the endpoints/outcome measures to be used.
  - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
  - Whether the research can be completed within the proposed period of performance.
- **Impact**
  - To what extent the project impacts a central critical problem or question in at least one FY19 PRMRP Topic Area.
  - If applicable, how well the proposed research project addresses one or more of the FY19 PRMRP Areas of Encouragement.
  - Whether the proposed research project, if successful, will make important scientific advances in the relevant field of research.

- To what degree the proposed project could, if successful, make a significant impact on the lives of relevant patient populations in the short term and/or long term.

- **Transition Plan**

  - Whether the identified next level of development and/or commercialization is realistic.

  - Whether the funding strategy described to bring the intervention to the next level of development (e.g., specific industry partners, specific funding opportunities to be applied for) is reasonable and achievable.

  - For Knowledge Products, whether the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable.

  - Whether the schedule and milestones for bringing the intervention to the next level of development (next-phase clinical trials, transition to industry, delivery to the market, incorporation into standard practice, and/or approval by the FDA) are achievable.

  - Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.

  - How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement.

- **Personnel**

  - Whether the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.

  - Whether the levels of effort by the PI and other key personnel are appropriate to ensure the successful conduct of the project.

  - How the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed work.

Scored review criteria for applications submitted to <u>Funding Level 4, which are of equal importance</u>:

- **Clinical Impact**
    - How relevant the anticipated outcomes of the proposed clinical trial are relevant to individuals affected by the specified disease/condition.
    - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
    - How the potential outcomes of the proposed clinical trial will provide/improve short-term benefits for individuals.
    - How significantly the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.
- **Research Strategy**
    - How well the scientific rationale for clinically testing the intervention is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/ preclinical evidence.
    - How well the study aims, hypotheses and/or objective(s), experimental design, methods, data collection procedures, and analyses are designed to answer clearly the clinical objective.
    - How well the inclusion and randomization criteria meet the needs of the proposed clinical trial.
    - How well the exclusion criteria are justified.
    - How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable.
    - To what degree the data collection instruments (e.g., surveys, questionnaires), if applicable, are appropriate to the proposed study.
- **Intervention**
    - Whether there is evidence of support indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
    - To what degree the intervention addresses the clinical need(s).
    - How the intervention compares with currently available interventions and/or standards of care.

- To what degree the application has provided preclinical and/or clinical evidence to support the safety of the intervention.
- How well research procedures are clearly delineated from routine clinical procedures.
- Whether measures are described to ensure the consistency of dosing of active ingredients for nutritional supplements (if applicable).

- **Statistical Plan**
  - To what degree the statistical model and data analysis plan are suitable for the planned study.
  - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
  - If applicable, whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.

- **Recruitment, Accrual, and Feasibility**
  - How well the application addresses the availability of human subjects for the clinical trial and the prospect of their participation.
  - Whether the application demonstrates access to the proposed human subjects population.
  - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial.
  - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.
  - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study (e.g., Will human subjects still be able to take their regular medications while participating in the clinical trial? Are human subjects required to stay overnight in a hospital?).

- **Ethical Considerations**
  - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
  - If applicable, how well the inclusion of international sites is justified.
  - How well the level of risk to human subjects is minimized and whether the safety monitoring and reporting plan is appropriate for the level of risk.

- Whether a research monitor with expertise consistent with the nature of the potential risk(s) is identified, if applicable.

- How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.

- To what degree privacy and confidentiality issues are appropriately considered.

- To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.

- **Transition Plan and Regulatory Strategy**

  - To what degree the regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well described.

  - Whether the application for Funding Level 4 without preclinical research includes documentation that the study is exempt from FDA or other international agency regulation, or that IND or IDE application (and/or international equivalent) has been submitted to the FDA and/or relevant international regulatory agency, as appropriate.

  - For investigator-sponsored regulatory exemptions (e.g., IND, IDE, or other international equivalent), whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA or relevant international regulatory agency.

  - Whether plans to comply with current GMP, GLP, and GCP guidelines are appropriate.

  - Whether the identified next level of development and/or commercialization is practical.

  - Whether the funding strategy described to bring the intervention to the next level of development (e.g., specific industry partners, specific funding opportunities to be applied for) is reasonable and achievable.

  - For Knowledge Products, whether the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable.

  - Whether the schedule and milestones for bringing the intervention to the next level of development (next-phase clinical trials, transition to industry, delivery to the market, incorporation into standard practice, and/or approval by the FDA) are achievable.

  - If applicable, whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.

- How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement.

- **Personnel and Communication**
  - Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
  - To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, and expertise in conducting clinical trials).
  - Whether the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
  - How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.
  - For multi-site clinical trials, how well the lead site responsibilities and human research protections regulatory coordination are defined and planned for.

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

- **Data and Resource Sharing**
  - To what degree the plan for sharing of project data and research resources is appropriate and reasonable to facilitate use by the wider research community.
- **Environment**
  - To what degree the scientific environment or clinical setting and the availability and accessibility of institutional resources support the proposed research (if applicable, at each participating center or institution).
  - How the quality and extent of organizational support are appropriate for the proposed research.
- **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.

- **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 PRMRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Relative accomplishments and outcomes from the initial PRMRP-funded award
    - Relevance to military health
    - 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 PRMRP 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

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

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the 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 will be required for Funding Levels 3 and 4.

Funding Level 4 in which some preclinical work is proposed in addition to the clinical trial, the clinical trial will be funded as an option: Report-out that application to the FDA (or equivalent international regulatory agency) has been submitted.

Funding Levels 3 and 4 Only: Report-out at one Milestone Meeting is required for this award mechanism.

In addition to written progress reports, annual Award Charts will be required. For the Expansion Award mechanism, use the format example "Award Chart" 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 20181120a. The Program Announcement numeric version code will match the General Applications Instructions version code 20181120.

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 is missing.

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Outcomes Statement (Attachment 5) is missing.

- Submission of the same research project to different Funding Opportunities within the FY19 PRMRP. Refer to Section II.D, Application and Submission Information, for exceptions.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

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

- An FY19 PRMRP 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 PRMRP Programmatic Panel members can be found at https://cdmrp.army.mil/prmrp/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 (http://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 may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- The proposed research project does not address at least one of the Congressionally directed FY19 PRMRP Topic Areas.

- A clinical trial is proposed in a Funding Level 1, 2, or 3 application.
- A clinical trial is **not** proposed in a Funding Level 4 application.
- An application to Funding Level 4 that does not include preclinical research and does not include proof of an IND or IDE application has been submitted to the FDA or relevant international regulatory agency, as appropriate, or does not include proof of an exemption that such regulatory oversight is not required.
- The PI does not meet the eligibility criteria.

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	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 and Lay Abstracts: Upload as Attachment 3 with file name "Abs.pdf"	
	Statement of Work: Upload as Attachment 4 with file name "SOW.pdf"	
	Outcomes Statement: Upload as Attachment 5 with file name "Outcomes.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Relevance to Military Health Statement: Upload as Attachment 7 with file name "MilRel.pdf"	
	Intervention: Upload as Attachment 8 with file name "Intervention.pdf" if applicable	
	Transition Plan and Regulatory Strategy: Upload as Attachment 9 with file name "TransStrat.pdf" if applicable	
	Human Subject Recruitment: Upload as Attachment 10 with file name "HumSubProc.pdf" if applicable	
	Study Personnel and Organization: Upload as Attachment 11 with file name "Personnel.pdf" if applicable	
	Data Management: Upload as Attachment 12 with file name "Data_Manage.pdf" if applicable	
	Surveys, Questionnaires, and other Data Collection Instruments: Upload as Attachment 13 with file name "Surveys.pdf" if applicable	

Application Components	Action	Completed
	Representations (Extramural submissions only): Upload as Attachment 14 with file name "RequiredReps.pdf" if applicable	
	DoD Military Budget Form(s): Upload as Attachment 15 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, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
B	Billion
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
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
PI	Principal Investigator
PRMRP	Peer Reviewed Medical Research Programs
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
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

APPENDIX 2: AREAS OF ENCOURAGEMENT

Applications addressing any of the FY19 PRMRP Topic Areas are of interest to the program. ***Any aspect of research relevant to one or more FY19 PRMRP Topic Areas may be considered for funding.*** Areas of encouragement related to each FY19 PRMRP Topic Area have been identified by the DoD, VA, and other relevant stakeholders and are listed below under each Topic Area. Applicants are urged to read and consider these areas of encouragement before preparing their applications. ***The information provided is not exhaustive, and applicants are not restricted to submitting applications that address an area of encouragement in this list.***

Acute Lung Injury

- Research on the etiology and prevention of acute lung injury (ALI)/acute respiratory distress syndrome (ARDS) caused by host responses to trauma, transfusion, burns, infection, hemorrhagic shock, inhalation, and/or oxygen exposure.

- Novel and/or innovative detection technologies or therapeutics to reduce the incidence and/or severity of ALI/ARDS and/or other lung injury secondary to trauma, transfusion, infection, burns, hemorrhagic shock, inhalation, and/or oxygen exposure.

- Strategies to stabilize and support the safe transport of patients with ALI/ARDS in order to optimize therapeutic interventions, particularly in operational scenarios requiring prolonged field care and/or longer transport times.

- Development of metrics to associate the long-term health outcomes of ALI/ARDS with physiological and physical performance.

Antimicrobial Resistance

- Development of novel and/or innovative interventions to prevent the spread of or treat infections from multi-drug-resistant organisms, focused on hardware-associated infections and biofilms.

- Development and/or testing of new diagnostics to distinguish between viral and bacterial infectious diseases that will inform treatment and limit the spread of antibiotic resistance.

- Development and evaluation of strategies to support healthy gut microbiome (such as prebiotics, probiotics, colostrum, vaccines, and small molecules) to slow emergence of antibiotic-resistant organisms that cause infectious diarrhea in training or deployment settings.

- Development of rapid diagnostics platforms to identify and characterize new pathogen-specific, drug resistance markers that can be used in austere settings and during prolonged field care (e.g., “omic” and systems biology approaches).

- Development of gene-editing tools (e.g., designer nucleases) that optimize treatment and raise the threshold for resistance to anti-infective agents.

Arthritis (other than Rheumatoid Arthritis or Post-Traumatic Osteoarthritis)

- Research quantifying the impacts of obesity, weight loss, physical fitness (all components, e.g., cardiovascular, strength, flexibility, balance), and dietary factors on the development of or prevention/risk reduction of arthritis.
- Studies to examine the use of regenerative medicine techniques and therapies (including cell-based therapies) to prevent or treat osteoarthritis, including dose-response information and the frequency and timing of application.
- Basic and translational research to identify treatments to mitigate and/or reverse osteoarthritis, particularly in the knee, hip, ankle, and shoulder.
- Identification and/or validation of biomarkers for early psoriatic arthritis.
- Research to establish activity recommendations for maximal joint life following joint repair, particularly in young patient populations.

Burn Pit Exposure

- Research on the etiology and treatment of adverse health events related to military deployment to Iraq and Afghanistan that are associated with exposure to airborne hazards and open pit burning of solid waste and other materials.
- Toxicological studies to characterize emissions from open air burns, burn boxes, and incinerators, and to ascertain the toxicity and mechanisms of action of such chemicals and airborne environmental dust and mixtures, as well as interactions among pollutants and particulate materials.
- Identification and validation of biomarkers of both exposure to and health effects of burn pit combustion products, burning biomass and refuse, and geogenic dusts.
- Development and validation of instruments for assessing (including in real time) levels of exposure to airborne hazards for use in research and for occupational and environmental exposure monitoring.

Cardiomyopathy

- Development of novel therapeutic approaches for primary and secondary cardiomyopathies.
- Strategies to identify risk factors associated with the development of cardiomyopathy (i.e., genetic, lifestyle, exposure) in the civilian and/or military populations.
- Research to improve the understanding of the pathophysiology of cardiomyopathies.
- Improvement of noninvasive diagnostic techniques for primary and secondary cardiomyopathies.
- Research on the multiple etiologies of cardiomyopathy (e.g., hypertension, ischemia, hemochromatosis, sleep apnea, radiation therapy, medications, smallpox vaccine, infections).

Cerebellar Ataxia

- Research to identify therapeutic targets and novel therapeutic modalities including gene silencing/gene editing.
- Research to improve the understanding of the causes of cerebellar ataxia.
- Research to improve the understanding of the association between lifestyle, environment, nutrition, and cerebellar ataxia.
- Research to better understand the role of physical rehabilitation/exercise in affecting postural disorders, balance, and coordination in cerebellar ataxia patients.

Chronic Migraine and Post-Traumatic Headache

- Precision medicine research to investigate, develop, and validate biomarkers to diagnose and monitor traumatic brain injury patients with chronic migraine or post-traumatic headache and to characterize individual responses to treatment.
- Epidemiological/natural history studies to characterize specific types of post-traumatic headache and chronic migraine, the pathobiology of these headaches (such as the role of acute cortical spreading depression after injury as a risk factor for chronic headaches of a migrainous type), and the risk factors that might predispose people to certain types of post-traumatic headache and chronic migraine.
- Research on the optimal approaches to effective management of acute and chronic pain and co-occurring psychological health disorders for chronic migraine and post-traumatic headache with a focus on assessing and eliminating adverse outcomes and decreasing polypharmacy.
- Evaluation of the efficacy of existing or emerging pharmaceutical interventions (non-opioid), as well as evaluation of mechanical stimulation and/or other non-pharmaceutical interventions, for the treatment of chronic migraine and post-traumatic headache.
- Evaluation of the differences in etiology, diagnosis, treatment plan, and prevention of migraine headaches between men and women.

Congenital Heart Disease

- Development of approaches, including regenerative medicine, that provide structural support, restore native activity, allow for tissue growth, and prevent the need for reoperation.
- Research to improve understanding of the causes of congenital heart defects, including genomic, proteomic, and metabolomic profiling.
- Research to design and implement disease-in-a-dish and/or microfluidic models with an established phenotype to increase the efficacy of finding novel and/or innovative drug targets, screen existing drugs, perform cardiotoxicity testing, and/or uncover pathogenesis.
- Research both on the risk of neurologic injury and on enhanced neuroprotection before, during, and after surgery for congenital heart disease.

- Population-based and outcomes-based research to assess the health outcomes of individuals with congenital heart disease across their life spans.

Constrictive Bronchiolitis

- Research to understand the role of occupational and environmental exposures, including military relevant volatile compounds, toxic industrial chemicals/materials in dense urban environments, and airborne particulates, such as mineral and soil dusts, in the etiology of constrictive bronchiolitis.

- Research to determine the prevalence and severity of constrictive bronchiolitis and related respiratory diseases in previously deployed military Service members and/or Veterans.

- Development and testing of minimally invasive or non-invasive approaches for diagnosing constrictive bronchiolitis.

- Research to develop novel and/or innovative therapeutics to modify the progression of constrictive bronchiolitis.

- Development and/or validation of animal models for understanding mechanisms and etiology of constrictive bronchiolitis.

Diabetes

- Research to better understand the heterogeneity of diabetes including the identification of novel biomarkers.

- Identification and/or evaluation of interventions to reduce the development of diabetes among individuals meeting the clinical criteria for pre-diabetes.

- Research on interventions to prevent or treat diabetes complications, including diabetic retinopathy, nephropathy, neuropathy, cardiomyopathy, and impaired wound healing.

- Research on the transplantation of allogenic or autologous pancreatic islet cells for long-term natural insulin production, including current good laboratory/clinical/manufacturing practices (as needed) for cell line development.

- Research to design and implement disease-in-a-dish and/or microfluidic models to model pancreatic islets to uncover pathogenesis and improve the efficiency of drug discovery.

Dystonia

- Research to improve identification of delayed onset dystonia following traumatic brain injury.

- Research on interventions to prevent, slow the progression of, or treat dystonia.

- Studies into the natural history, genetics, and/or neurobiology of dystonia.

- Research to identify the relationship between specific molecular/genetic changes and circuitry/network alterations in dystonia.

- Identification and development of novel research tools (such as cellular models, phenotypic models, etc.) to aid dystonia research.

Eating Disorders

- Investigations into the prevalence, diagnosis, and treatment patterns of eating disorders in Service members and their families, including potential relationships with military-unique behaviors or conditions.

- Assessment of patterns of comorbidity between eating disorders and other mental health conditions, including an examination of whether eating disorders are more likely to precede or follow the development of other mental health conditions.

- Studies to identify the most effective treatments (and order of treatment) for patients with an eating disorder and a comorbid disorder.

- Research to advance the understanding of the biological, genetic, lifestyle, and environmental factors that influence eating disorders.

- Studies to elucidate and/or mitigate risk factors for the onset or recurrence of eating disorders, including social influences.

Emerging Infectious Diseases

- Surveillance and predictive modeling tools that leverage artificial intelligence approaches to predict outbreaks and epidemics and support strategies for mitigating the threat of emerging infectious diseases (e.g., dengue, malaria, Hanta).

- Research and development of in silico and/or in vitro tools to assess product manufacturability/developability, efficacy, and toxicity, such as cells-on-a-chip and 3D tissue modeling, to support development of medical countermeasures.

- Development of a wearable sensor that provides real-time diagnostics of naturally occurring infectious diseases to predict illness before onset of symptoms.

- Rapid prediction of protective antigens/epitopes and testable correlates of protection on emerging or novel pathogens.

- Development of highly sensitive diagnostic system for use at the point of need that provides early diagnosis of infection prior to the onset of classical symptoms.

- Research, development, and validation of animal models for the study of infectious diseases that clearly show the pathophysiological mechanism of the disease and provide translational data to advance drug products to human clinical trial.

- Development of risk assessment strategies for vector-borne diseases and novel interventions for vector control, including but not limited to novel insecticides, larvicide applications, and barrier methods.

Epidermolysis Bullosa

- Research, including clinical trials, focused on therapeutics (topical or systemic) or dressings that enhance wound healing in inherited epidermolysis bullosa.
- Development of novel therapeutics to reduce epidermolysis bullosa symptoms, improve quality of life, or lead to a cure.
- Research to provide further insight into those cellular pathways that promote the development of squamous cell carcinomas in recessive dystrophic and junctional epidermolysis bullosa.
- Research, including randomized controlled clinical trials, focused on systemic drugs that prevent, delay the onset, or modify the aggressiveness of squamous cell carcinoma in patients with recessive dystrophic and junctional epidermolysis bullosa.

Focal Segmental Glomerulosclerosis

- Research to improve understanding of the causes of primary and/or secondary focal segmental glomerulosclerosis (especially genetic mutations).
- Development of non-invasive methods to diagnose focal segmental glomerulosclerosis and its variants.
- Development of a curative therapy or treatments to delay or halt the progression of focal segmental glomerulosclerosis and/or prevent post-transplantation recurrence.
- Research to determine the efficacy of medications used off-label (outside the FDA-approved indication) to treat focal segmental glomerulosclerosis.

Frontotemporal Degeneration

- Basic research to establish in vivo and in vitro models for disease pathology, behavioral/cognitive symptoms, and motor dysfunction.
- Research to understand the neurological basis of deficits in social cognition and emotional regulation.
- Research to improve diagnostics of and/or prognostics for frontotemporal degeneration.
- Research to identify risk factors (e.g., gene networks, environmental factors, and family history of dementia).
- Development of evidence-based non-pharmacological and/or pharmacological treatments for frontotemporal degeneration and associated symptoms.

Guillain-Barré Syndrome

- Development of a rapid diagnostic test for Guillain-Barré syndrome.
- Research on the immune system cell types and molecular mechanisms responsible for the pathology of Guillain-Barré syndrome.

- Research to elucidate the characteristics of various exposures (e.g., viruses, bacteria, vaccinations, surgery, trauma) associated with Guillain-Barré syndrome and their effects on the immune system.

- Research to prevent or reduce the effects of residual weakness, relapse of muscle weakness, and other neurological and psychological symptoms of Guillain-Barré syndrome to improve patients' quality of life and increase their independence.

- Development of new treatments and refinement of existing treatments for Guillain-Barré syndrome.

Hemorrhage Control

- Development of new and innovative capabilities to stop non-compressible intracavitary hemorrhage and improved technologies to stop junctional and pelvic bleeding in pre-hospital environments.

- Development of innovative damage control resuscitation and damage control surgical capabilities.

- Research on strategies for early (e.g., pre-hospital) detection (especially internal bleeding) and treatment for hemorrhage, coagulopathy of trauma, and hemodynamic decompensation/ hypovolemic shock.

- Research on novel or engineered blood products that offer physiological, logistical, or cost advantages over current products. Proposals for HBOCs should address nitric oxide scavenging.

- Research on adjunctive pharmacological solutions for hemorrhage, shock, coagulopathy, transfusion, and/or the stabilization of polytrauma, with attention to contraindications and/or impact on TBI.

- Research to evaluate the effects of current combat blood product transfusion guidelines on immunological status and clinical outcomes.

Hepatitis B

- Identification and reduction of hepatitis B in blood products for transfusion.

- Research on strategies to reduce vertical (mother-to-child) transmission of hepatitis B.

- Development of strategies for reliable, non-invasive, early detection of hepatitis-related liver disease and hepatocellular carcinoma.

- Research on strategies to promote reversal of liver fibrosis and/or assess the associated clinical and pathological outcomes.

- Clinical studies to evaluate combination or curative therapies for treatment of hepatitis B infection.

Hereditary Angioedema

- Research toward the development of a cure for hereditary angioedema.
- Development and/or validation of novel and/or innovative therapeutic strategies for the treatment and/or prevention of hereditary angioedema attacks.
- Research to improve early diagnosis of hereditary angioedema.
- Evaluation of existing, innovative, or novel therapeutics in pediatric hereditary angioedema patients.

Hydrocephalus

- Research on the etiology, prevention, diagnosis, and treatment of post-traumatic hydrocephalus.
- Discovery or validation of novel and/or innovative therapies and therapeutic targets for the treatment of hydrocephalus and its sequelae, including therapies directed at myelin regeneration and repair.
- Development or validation of biomarkers and imaging techniques, particularly multimodal approaches, to aid in diagnosis, prognosis, and monitoring of therapeutic efficacy.
- Research on the prevention of shunt failure or the development of novel shunt technologies.
- Development or validation of improved hydrocephalus model systems.

Immunomonitoring of Intestinal Transplants

- Studies to elucidate the role of the mucosal immune system, humoral, innate, and adaptive cellular immunity, other host-derived factors, or gut microbiota-derived factors in maintaining intestinal transplant viability and improving outcomes.
- Development and evaluation of evidence-based intestinal transplant strategies that focus on dampening the immune response against intestinal transplants or circumvent the induction of immunity against the transplant.
- Development and evaluation of implant-associated materials (e.g., scaffolds) with anti-inflammatory properties that protect the intestinal transplant from immune attack.
- Development and evaluation of strategies for inducing and maintaining populations of anti-inflammatory regulatory immune cell populations at the transplant site.
- Studies to improve immunomonitoring of recipient immune responses after intestinal transplantation, with a focus on prospective leukocyte profiling, to aid in diagnosis and treatment of immunological and immunosuppression-related complications.
- Development and/or validation of precise, real-time implanted monitoring devices to improve individualized patient outcomes after intestinal transplantation.

Inflammatory Bowel Diseases

- Studies directed toward understanding how acute enteric infections may trigger chronic inflammatory bowel diseases.
- Studies that leverage genomic, microbiomic, immunological, and systems biology approaches to prevent inflammatory bowel disease (especially inflammatory bowel diseases associated with acute enteric infection).
- Studies to understand the interaction between acute/chronic stress and infection and their influence on inflammatory bowel diseases.
- Research to better characterize the association between the use of drugs, such as isotretinoin and long-term doxycycline, and the development of inflammatory bowel diseases.
- Research on the role of diet in the development and progression of inflammatory bowel diseases.
- Research on treatment strategies for patients with inflammatory bowel diseases to include, but not limited to, rebalancing the microbiome, pre- and probiotics use or colostrum products, including those who are refractory to standard care.

Interstitial Cystitis

- Studies that define the risk, prevalence, and operational impact of interstitial cystitis among active duty personnel.
- Identification and validation of biomarkers for making a definitive diagnosis of interstitial cystitis.
- Evaluation and assessment of novel and/or innovative treatment options for interstitial cystitis patients, including intravesical therapy.
- Research on the etiology and pathogenesis of interstitial cystitis to inform targeted therapy development.

Lung Injury

- Studies to identify the prevalence and associated morbidity and mortality of blast overpressure lung injury.
- Development of improved methods for assessing lung injury due to exposure to chemical or physical (e.g., radiation) hazards and materials in occupational, operational, and training environments to improve surveillance, diagnosis, and prognosis.
- Development of improved methods for monitoring pulmonary exposure to chemical or physical agents that might cause lung injury.
- Identification of pre-existing conditions that predispose an individual’s susceptibility to lung injury resulting from environmental exposures (i.e., genetic predisposition).

- Development of novel preventive techniques, detection technologies, and therapeutics to reduce the incidence and/or severity of lung injury.

Metals Toxicology

- Identification and validation of biomarkers to evaluate military Service members' acute exposure to toxic metals in an operational environment and predict potential consequent health risks and associated health outcomes.

- Retrospective studies to evaluate risks and exposure to military-relevant toxic metals among workers at industrial facilities.

- Research on the toxicity of metal combinations and the interaction between different metal components.

- Research on the toxicity of metal-based engineered nanomaterials, including those used in military applications.

- Development of microsurgical techniques to remove embedded toxic metals.

Mitochondrial Disease

- Identification and testing of non-invasive techniques and biomarkers to monitor mitochondrial function, aid in clinical diagnosis, and/or evaluate therapeutic efficacy.

- Development of improved tools and animal models to study primary mitochondrial diseases and evaluate therapeutics.

- Research to better understand the pathology of primary mitochondrial diseases.

- Development of tools and methodologies to assess mitochondrial heteroplasmy on a cellular, tissue, and organ level.

- Research on novel and/or innovative treatments to alleviate symptoms or slow down the progression of mitochondrial diseases.

Musculoskeletal Disorders

- Research on computational models that provide personalized, actionable information regarding the physical resilience of the musculoskeletal system for the prevention and treatment of musculoskeletal disorders such as load carriage capability, effectiveness of physical training and treatments, and effective use of exoskeleton technology.

- Development and/or validation of metrics (clinical-based measures/tools and field-based measures/tools) to inform readiness and/or return-to-duty/work decision making following the management, treatment, and rehabilitation of musculoskeletal disorders.

- Research to increase understanding and to improve diagnosis, prevention, and/or treatment of chronic overuse musculoskeletal disorders.

- Research on back pain treatment and/or management strategies to prevent surgery and recurrence of symptoms, identify factors that predict optimal treatment response for different patients, and encourage self-management.

Myotonic Dystrophy

- Research on the role of epigenetic factors in the onset, progression, and/or severity of myotonic dystrophy in relevant animal models or patients.
- Research into the mechanisms of expanded CTG or CCTG repeat instability in somatic or germ line cells in myotonic dystrophy.
- Identification of biomarkers that can be detected through minimally invasive means to signal early changes in the progression of myotonic dystrophy.
- Development and/or testing of novel and/or innovative treatments, including those utilizing gene editing or silencing.
- Clinical research into the natural history of myotonic dystrophy, to understand disease progression and develop/validate clinical trial endpoint measures across the multiple organ systems involved in the disease.

Nanomaterials for Bone Regeneration

- Research on nanomaterials that stimulate vascularization and new bone growth.
- Research on nanomaterials-based methods to facilitate recruitment of endogenous cell populations for enhanced bone regeneration and osseointegration.
- Development of nanomaterial-based technologies addressing segmental/large bone defects in craniomaxillofacial and/or load-bearing regions.
- Development of nanomaterials for controlled release/extended release of growth factors for bone regeneration.
- Development of nanomaterial-based technologies that repair the soft tissue envelope to enhance bone regeneration.

Nutrition Optimization

- Development and/or validation of nutrition-based strategies that mitigate the consequences of stressors, especially on Service member health, readiness, and performance.
- Development of prolonged nutrition care using oral and/or intravenous approaches including precision nutrition care following injury or illness.
- Research on the impact of the use of dietary supplements (e.g., vitamins, probiotics, protein powders) on the physical and/or cognitive performance, including the readiness of military Service members.

- Development and/or validation of improved nutrition strategies for physical and/or cognitive performance enhancement and sustainment in operational environments and efforts to optimize nutrition in resource-limited settings.

- Research to develop strategies to apply metabolomics to optimize individual nutrition and the development of tools or devices to monitor nutritional intake at an individual level.

Pancreatitis

- Development and testing of novel and/or innovative therapeutics for acute and/or chronic pancreatitis.

- Research on the basic biology and physiology of the pancreas to better understand the etiology and pathology of pancreatitis.

- Research to improve understanding and management of complications of pancreatitis.

Pathogen-Inactivated Blood Products

- Research on lyophilization of pathogen-reduced/-inactivated blood products and derivatives (platelets, plasma, red cells, cryoprecipitate, coagulation factors, etc.).

- Development and advancement of technologies to improve the safety of blood products to include pathogen reduction/inactivation in whole blood for military/civilian blood donor centers and blood banks that meet the requirements for FDA licensure in support of domestic and global contingency/combat operations.

- Expansion and validation of the library of blood-borne pathogens that are reduced/inactivated to include emerging pathogens, genetically modified pathogens, and pathogens designed for biological warfare.

- Advancement in pathogen reduction technology to further improve the log-kill reduction for blood-borne pathogens (e.g., Hepatitis B, Korean Hemorrhagic Fever virus, Bunyan virus, HIV, Rift Valley Fever, Malaria, Babesia, Ebola, West Nile virus, Dengue, Chikungunya, Zika virus).

- Research studies, including clinical trials, to further characterize the effects of pathogen reduction technologies in blood products (e.g., whole blood, platelets, plasma, cryoprecipitate).

- Development and validation of next-generation technologies and/or devices to reduce the production time for pathogen reduction/inactivation in whole blood.

Polycystic Kidney Disease

- Development of improved treatment strategies for polycystic kidney disease, including approaches to identify and monitor patients at higher risk for progressing to end-stage renal disease.

- Research on the underlying pathobiology and molecular mechanisms of polycystic kidney disease, including studies of genetic factors, cyst formation and growth, the role of cilia, and factors that modify disease progression and/or severity.

- Research on the lifestyle factors or comorbidities that may modify the progression of polycystic kidney disease.

Post-Traumatic Osteoarthritis

- Development or validation of innovative regenerative rehabilitation approaches for preventing or mitigating post-traumatic osteoarthritis.

- Studies to evaluate and develop best practices for multidisciplinary team approaches and treatment algorithms for post-traumatic osteoarthritis.

- Intra-articular treatments that offer sustained (two or more months) relief of symptoms and/or disease-modifying effects.

- Research on therapies that target multiple phases of the cellular response pathways that are implicated in the development of post-traumatic osteoarthritis, including cell death, inflammation, matrix changes, and changes in catabolic and anabolic responses.

- Research on biomarkers that can serve as surrogate endpoints for post-traumatic osteoarthritis diagnosis and/or can optimize subject selection in clinical trials.

Pressure Ulcers

- Novel strategies for the treatment of pressure ulcers including mitigation of progression to advanced stages.

- Strategies to prevent or reduce the formation of pressure ulcers during prolonged immobilization of casualties in a pre-hospital environment (e.g., spinal cord injuries) or long-range transport/aeromedical evacuation.

- Research on novel techniques for synthetic production, delivery, and adhesion methodologies leading to permanent closing of pressure ulcers. This might encompass synthetic fibers, novel tissue culture methodologies, growth factors, dermal printing, artificial skin, skin graft substitutes, regenerative medicine, etc.

- Novel strategies for the prevention or early detection of pressure ulcers.

Pulmonary Fibrosis

- Identification of biomarkers of pulmonary injury or early predictors of interstitial lung disease.

- Development and/or validation of improved tools and animal models (excluding mice) to study pulmonary fibrosis and evaluate therapeutics.

- Research into the pathobiology and molecular mechanisms underlying the development and progression of pulmonary fibrosis.

- Retrospective studies to determine the risk and incidence of pulmonary fibrosis among military Service members and/or Veterans.

- Development and/or testing of novel and/or innovative treatments, to include precision medicine approaches, to delay or modify the progression of pulmonary fibrosis.

Resilience Training

- Research to deliver evidence-based interventions and improved comprehensive strategies for building individual, family, and community resilience to physical, psychological, environmental, and social stressors over the military life cycle, including transitions.

- Research that measures the effects of resilience training approaches on a broad array of outcomes and constructs of interest (physical health, performance, well-being, mental health, relationships, etc.) by evaluating the efficacy of resilience training and/or leadership approaches in response to stressors and challenges.

- Development and validation of physical or psychological measures of individual variation and response to stressors and meaningful resilience measures, including non-self-report objective measures.

- Research aimed at understanding the relationship between Service member resilience and successful/unsuccessful recovery from injury.

- Research in psychometric training or pharmacological treatment(s) to manage stress within individuals.

Respiratory Health (excludes lung cancer and mesothelioma)

- Research on the causes, treatment, and prevention of obstructive pulmonary diseases (e.g., chronic obstructive pulmonary disease and bronchiectasis), including identification and validation of biomarkers and disease phenotypes, as well as employing personalized medicine in clinical research and disease management.

- Research on the cause, treatment, and prevention of respiratory symptoms and ailments possibly associated with deployed and redeployed military personnel.

- Research to evaluate the impact of military service, primarily deployment, on the prevalence and severity of respiratory disease.

- Identification and/or validation of biochemical, physiological, or combined biomarkers for evaluating risk or extent of pulmonary injury from either acute or long-term toxic occupational or environmental exposures.

- Research investigating exposure rates, detection, and treatment of diseases related to inhalation of mold and fungi, such as coccidioidomycosis from both indoor and outdoor sources.

Rett Syndrome

- Identification and/or validation of novel and/or innovative biological targets for the treatment of Rett syndrome.
- Development and testing of interventions to improve the neurological symptoms of Rett syndrome.
- Research to understand the relationship between genetic mutations, physical traits, and symptoms in individuals with Rett syndrome.
- Research to understand Rett syndrome's commonalities with, and differences from, other autism spectrum disorders.
- Research on the pathobiology of MeCP2 and associated genes and proteins.

Rheumatoid Arthritis

- Research to better understand the relationship between genetic risk, environmental exposures, and predicted triggers, such as infection or smoking, in developing rheumatoid arthritis.
- Studies that identify or validate biomarkers or personalized medicine strategies that allow for individualized medication choice based on the patient's underlying biology or disease state.
- Research on the long-term use of immunosuppressive and other therapies in patients with rheumatoid arthritis.
- Research to better characterize and understand the preclinical disease stage of rheumatoid arthritis for early diagnosis and treatment.
- Research on management of comorbidities, including biopsychosocial outcomes, for patients with rheumatoid arthritis.
- Research to establish activity recommendations following joint replacement for maximal joint life.

Scleroderma

- Research on the molecular mechanisms and pathogenesis of scleroderma, including the identification of novel and/or innovative therapeutic targets.
- Development and/or validation of novel and/or innovative therapies for scleroderma.
- Identification and/or validation of biomarkers and other approaches for early diagnoses, monitoring disease progression, and/or assessment of treatment response.
- Epidemiologic studies investigating the impact of localized scleroderma (morphea) on duty performance, use of personal protective equipment, and deployability.
- Research on early identification and prevention of scleroderma-associated complications, such as lung, liver, or kidney disease.

Sleep Disorders

- Research on how the disruption of normal sleep and circadian rhythms adversely affects the physical and psychological health, safety, performance, and productivity of military personnel and civilian populations, including sex and gender differences.

- Identification and/or validation of non-Continuous Positive Air Pressure (CPAP)-based treatment regimens that enhance compliance in military personnel and civilian populations.

- Research on the prevention and/or mitigation of sleep disorders that are associated with long aeromedical evacuation flights for both clinical team members and patients.

- Development and/or testing of non-pharmacological treatments for sleep disorders associated with long-term exposure to enclosed environments (e.g., aircraft, submarines, tanks).

- Research on the precision diagnosis and/or treatment of sleep disorders, especially following traumatic brain injury or related to post-traumatic stress disorder.

Spinal Muscular Atrophy

- Research into molecular and proteomic phenotyping the spinal muscular atrophy disease state.

- Research to determine mitochondrial involvement and astrocytic and other non-neuronal contributions to motor neuron vulnerability.

- Exploration of the form and function of SMN-depleted neuromuscular junctions at ultrastructural (e.g., dysregulation of endocytosis), transcriptomic, and proteomic levels, particularly the mildest SMN reduction that leads to consistent quantifiable motor neuron loss.

- Research to find non-SMN-altering spinal muscular atrophy modifying genes that may lead to identification of novel and/or innovative therapeutic targets or treatments.

- Research to further understand SMN gene regulation and post-transcriptional mechanisms leading to synergistic SMN-repleting approaches, as well as to determine whether boosting SMN induction maximizes efficacy.

Tinnitus

- Development and validation of objective tools/methods to diagnose and characterize tinnitus (e.g., imaging techniques to identify functional and structural changes in the brain, biomarkers of resiliency, and susceptibility to tinnitus).

- Research to understand the mechanisms of tinnitus, its relationship to noise-induced hearing loss, and progression to chronic tinnitus, with the focus on developing interventions.

- Research to understand and mitigate the negative impact of tinnitus on operational readiness of the military.

- Identification of novel and/or innovative therapies and/or devices for interventions to prevent, manage, and treat tinnitus, including behavioral approaches, new uses for existing drugs, nutritional and pharmaceutical strategies, and acoustic, electrical, and other stimulation technologies.

Tissue Regeneration

- Development of novel therapies to repair neurosensory damage, maintain the distal end organ interface, or regenerate the neuromuscular junction for reinnervation of end organs during peripheral nerve regeneration.

- Development of novel therapies for regeneration of tendons and musculotendinous junctions.

- Development of novel therapies for regeneration of functional skeletal muscle, particularly (1) stem cell-based approaches and (2) treatments for volumetric muscle loss.

- Research on novel approaches and therapies to understand mechanisms of immune rejection and obviate the need for chronic toxic immunosuppression in reconstructive transplantation and vascularized composite allotransplantation.

- Research into innovative methods for developing biocompatible scaffolds and stem cell therapies for manufacturing and production of tissues.

- Research on novel interventions to regenerate brain tissue and recover neurological function, especially following traumatic brain injury.

Tuberculosis

- Research to understand, diagnose, or treat multi-drug-resistant tuberculosis or extensively drug-resistant tuberculosis.

- Development of novel strategies or therapeutics to treat tuberculosis.

- Development of a diagnostic assay that can be used at the point of care to rapidly and accurately diagnose tuberculosis to include multi-drug-resistant tuberculosis or extensively drug-resistant tuberculosis.

- Development of novel and/or innovative tuberculosis vaccines or optimization of current tuberculosis vaccines.

Vascular Malformations

- Studies into the natural history, genetics, and pathogenesis of vascular malformations.

- Research to develop or improve methods to diagnose and manage vascular malformations.

- Research to discover or develop novel and/or innovative therapeutic targets and treatments to regress or prevent vascular malformations.

- Development of non-invasive or minimally invasive technologies or approaches for the control of internal bleeding, including cerebral arteriovenous malformations, associated with vascular malformations.

- Development of in vivo or in vitro models of vascular malformations for the purpose of identifying novel and/or innovative drug targets, screening existing drugs, and/or elucidating the pathogenesis of the disease.

Women's Heart Disease

- Identification of sex-specific approaches to either develop novel diagnostics and treatments or increase the effectiveness of current practice to improve clinical care of women.

- Research on factors to predict and prevent the long-term impacts of the endocrine system, gestational diabetes, gestational hypertension, menopause, or preeclampsia on the cardiovascular health of women.

- Research on trauma-induced cardiac arrest secondary to hemorrhage and polytrauma in the female population.

- Research focused on elucidating the potential relationship between post-traumatic stress disorder and women's heart disease.

- Studies to determine the risk and incidence of heart disease among current and/or former female Service members.

APPENDIX 3: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DoD and VA areas of research interest, ongoing research or potential opportunities for collaboration within the FY19 PRMRP Topic Areas.

Air Force Office of Scientific Research
https://www.wpafb.af.mil/afrl/afosr/

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

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

Clinical and Rehabilitative Medicine Research Program
https://crmrp.amedd.army.mil

Combat Casualty Care Research Program
https://ccc.amedd.army.mil

Congressionally Directed Medical Research Programs
https://cdmrp.army.mil

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

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

Defense Threat Reduction Agency
http://www.dtra.mil/

Military Health System Research Symposium
https://mhsrs.amedd.army.mil/SitePages/Home.aspx

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

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

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

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

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

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

Telemedicine and Advanced Technology Research Center
http://www.tatrc.org/

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

U.S. Army Institute of Surgical Research
https://www.usaisr.amedd.army.mil/

U.S. Army Medical Materiel Development Activity
https://www.usammda.army.mil/

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

U.S. Army Medical Research Institute of Infectious Diseases
https://www.usamriid.army.mil/

U.S. Army Research Institute of Environmental Medicine
https://www.usariem.army.mil/

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

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.amedd.army.mil/

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

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

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

General Application Instructions

Version 20181120

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Table of Contents

This General Application Instructions document must be read in conjunction with the Program Announcement for this funding opportunity, which is available for downloading from Grants.gov and eBRAP.org.

I. HELPFUL INFORMATION

A. Tips for Success

This symbol marks helpful hints throughout this document.

This symbol refers the reader to the Program Announcement for specific instructions.

B. Applicant Organizations

Applications may be submitted by extramural organizations and intramural Department of Defense (DoD) organizations, defined as follows:

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

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

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

C. Current Funding Opportunities

All funding opportunities currently offered through the U.S. Army Medical Research and Materiel Command (USAMRMC), including those issued by the Congressionally Directed Medical Research Programs (CDMRP), may be viewed at https://www.grants.gov; when performing a search users should enter Catalog of Federal Domestic Assistance (CFDA) Number 12.420. Information about funding opportunities may also be found on the CDMRP website at https://cdmrp.army.mil/funding/ and on the CDMRP's electronic Biomedical Research Application Portal (eBRAP) website at https://ebrap.org/eBRAP/public/Program.htm. To receive email notification of CDMRP funding opportunity releases, subscribe to program-specific news and updates under "Email Subscriptions" on eBRAP's home page (https://ebrap.org/eBRAP/programSubscription/Subscribe.htm). Email notifications of funding opportunities are sent as a courtesy and should not be used as the sole source of notification; applicants should subscribe on Grants.gov to receive notifications of updates and new grant opportunity postings (https://www.grants.gov/web/grants/manage-subscriptions.html).

To ensure accurate referencing, please verify that the eight-digit (numeric) version number on the General Application Instructions matches the version number of the Program Announcement found in Section II.H.1, "Program Announcement and General Application Instructions Versions," of the Program Announcement.

D. Receiving Emails from CDMRP, eBRAP, and Grants.gov

To help ensure that all email correspondence is delivered correctly and is not treated as spam, keep your email address up to date in eBRAP (intramural and extramural applicants) and/or Grants.gov (extramural applicants), and place the following domains into your safelist: army.mil, us.army.mil, *.mail.mil, eBRAP.org, and Grants.gov. Use the same email address when submitting both the pre-application and the full application.

Modification to the the full application package may occur. The applicant is responsible for using the latest version of the full application package. Applications submitted without the required components of the full application package may be rejected. Applicants are encouraged to sign up to receive notifications of any changes to the funding opportunity (https://www.grants.gov/) through either **(1)** the "Send me change notification emails" link on the Synopsis page for the specific Program Announcement or **(2)** by responding to the Grants.gov prompt *when first downloading the Grants.gov application package* (extramural applicants only).

E. Agency Contacts

1. **CDMRP Help Desk:** Questions related to Program Announcement content or submission requirements, as well as questions related to submission of pre-applications (extramural and intramural submissions) or full applications (intramural submissions only) 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. Eastern time. Response times may vary depending on the volume of inquiries. The CDMRP Help Desk will not provide Grants.gov submission assistance.

   Phone: 301-682-5507 (Monday through Friday, 8:00 a.m. to 5:00 p.m.)
   Email: help@eBRAP.org

2. **Extramural Submissions - Grants.gov Contact Center:** Questions related to application submission through the 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).

   Phone: 800-518-4726; International 1-606-545-5035
   Email: support@grants.gov

F. Application Submission Overview

Application submission is a two-step process.

STEP 1. Pre-application submission: All pre-applications for both extramural and intramural organizations ***must*** be submitted through eBRAP (https://eBRAP.org/).

STEP 2. Full application submission: Full applications must be submitted through the online portals as described below.

Extramural Application Submissions*:** Full applications from extramural organizations ***must be submitted through Grants.gov Workspace (refer to Section III, Application Submission for Extramural Organizations). Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators are considered extramural submissions. Full applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn.

Intramural Application Submissions: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural organizations that are unable to submit to Grants.gov should submit through eBRAP (refer to Section IV). Intramural 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.

All pre-application and application components must be submitted by the deadlines stipulated on the title page of the Program Announcement. Failure to meet any of the deadlines will result in application rejection.

Submission of applications from U.S. Federal agencies and those proposing collaborations with Military Facilities have unique requirements. Budget requirements and restrictions apply. See Section III.A.5, Research & Related Budget and Section III.A.8, DoD Military Budget Form.

For guidance regarding changes to the Principal Investigator (PI) or organization, refer to Appendix 2, Section B, and to the specific Program Announcement.

II. eBRAP REGISTRATION AND PRE-APPLICATION SUBMISSION

General eBRAP registration information is provided below (Section II.A). For detailed instructions, refer to the eBRAP User Guide (https://ebrap.org/eBRAP/public/UserGuide.pdf) for eBRAP registration and www.grants.gov for Grants.gov registration.

A. Registration Requirements (All Applicants)

eBRAP Registration

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 throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement requirements, and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy and to ensure proper ordering as specified in the Program Announcement.

eBRAP does not confirm the accuracy of file content.

PIs must be registered in eBRAP to submit a pre-application.

PIs are encouraged to start the registration processes for eBRAP early to ensure that there is sufficient time for completion prior to the submission deadline. There is no grace period.

Extramural Submissions: *Application submitted by a non-DoD organization to Grants.gov.* Applicants should ensure that their name and email address are the same as the name and email address on the Standard Form 424 Research and Related (SF424 Research & Related) Form of the Grants.gov application package submitted through Grants.gov Workspace.

Intramural Submissions: *Application submitted by a DoD organization for an intramural investigator who is a DoD military or civilian employee working within a DoD laboratory or Military Treatment Facility or in a DoD activity embedded within a civilian medical center.* Applicants should ensure that their name and email address are the same as the name and email address that will be provided within the full application package through eBRAP for intramural applicants.

PIs with an Open Researcher and Contributor ID (ORCID) identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

During eBRAP registration, the PI must request to be affiliated with his/her organization from the list of organizations already registered with eBRAP. If the PI's organization is not already registered with eBRAP, then the PI must invite an Authorized Organizational Representative (AOR) to register the organization. The AOR does not need to complete the organization registration in eBRAP prior to the pre-application submission deadline in order for the pre-application to be submitted. However, before the full application submission deadline, the organization's eBRAP registration must be complete to allow for processing, viewing, and modifying of the full application package components.

Specific information must be identical between the pre-application and the full application for eBRAP to process an application. The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP.

B. Content and Form of Pre-Application Submission

For specific instructions regarding content of the pre-application submission components, refer to the Program Announcement.

All pre-application components must be submitted through eBRAP (https://eBRAP.org/) by the deadline specified in the Program Announcement. Click on "Submit" and "Confirm Submission" to complete the pre-application submission.

During pre-application submission, the PI must identify a Business Official from the list of Business Officials registered with eBRAP. If the PI's Business Official is not already registered with eBRAP, the PI must invite the Business Official to register. This invitation to register must be sent prior to the pre-application deadline. The Business Official's registration must be completed prior to the full application deadline to allow the Business Official to view/modify the full application files in eBRAP after submission.

During pre-application submission, the PI must select the performing organization (site at which the PI will perform the proposed work) and contracting organization (organization submitting on behalf of the PI) and click on "Add Organizations to this Pre-application." The organization(s) must be either selected from the eBRAP drop-down list or invited to allow submission of the pre-application.

The pre-application consists of the following components, organized in eBRAP by separate tabs:

Tab 1 – Application Information: Enter the application information as described in eBRAP before continuing the pre-application. Submission of application information includes assignment of primary and secondary research classification codes, which can be found at https://ebrap.org/eBRAP/public/Program.htmThe codes have been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection. Click on "Save."

Tab 2 – Application Contacts: Enter contact information for the PI. Enter the name of the organization's Business Official responsible for sponsored program administration. Depending on screen resolution, scrolling horizontally may be necessary to locate the box to "Invite an AOR" to register the performing and/or contracting organizations. Click on "Add Organizations to this Pre-application." The Business Official must be either selected from the eBRAP list or invited to allow the pre-application to be submitted. **If the Business Official cannot be found in eBRAP, an invitation must be sent to him/her to register in eBRAP.**

Tab 3 – Collaborators and Key Personnel: Enter the name, organization, and role of all collaborators and key personnel associated with the application. Click on "Save."

CDMRP does not follow National Institutes of Health (NIH) guidelines for role designation of project participants. Unless otherwise noted in the Program Announcement (e.g., Partnering PIs), applicants should assign the role of each participant in accordance with the participant's respective involvement in the project.

No member of the Programmatic Panel may be named as being involved in the research proposed or found to have assisted in the pre-application or application processes. Refer to the specific Program Announcement for a link to the list of Programmatic Panel members.

If formal collaboration with Military Facility personnel is planned (i.e., included in the application in performance of the research), those Military Facility personnel are prohibited from being involved in the review process and/or with making funding recommendations.

Tab 4 – Conflicts of Interest: To avoid COIs during the screening and review processes, 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). Click on "Save."

Tab 5 – Pre-Application Files: Upload all documents as PDF as specified in the Program Announcement. Documents should conform to the formatting guidelines outlined in Appendix 4. Click on "Upload."

- eBRAP will truncate characters exceeding the limit specified for each data field as specified in the Program Announcement.
- eBRAP will not allow a document to be uploaded in the "Required Files" tab if the number of pages exceeds the limits specified in the Program Announcement.

Tab 6 – Submit Pre-Application: Enter eBRAP password and click the "Submit" button. Click the "Confirm Submission" button to complete the pre-application submission. ***This finalizes the pre-application process.***

The pre-application is not submitted until Tab 6 is complete. Pre-applications not completed remain in DRAFT status.

Following completion of pre-application submission, the status of the pre-application in eBRAP will change from "DRAFT" to "SUBMITTED" and a confirmation email will be sent to the PI and named Business Official. ***An applicant with a pre-application in DRAFT status after the pre-application submission deadline is ineligible to submit an application. Check the status of the pre-application. There are no grace periods.***

III. APPLICATION SUBMISSION FOR EXTRAMURAL ORGANIZATIONS

Grants.gov applicants must apply online using Workspace. Workspace is a shared online environment where members of a grant team (investigators and business officials) may simultaneously access and edit different webforms within an application. Applicants must create a Workspace, invite grant team members to join the Workspace, complete the required forms, and submit their application Workspace package.

To apply through Grants.gov, an organization must first complete the Grants.gov registration process. ***Allow up to 8 weeks for the completion of the Grants.gov registration process***. Registering early is advised.

Foreign organizations doing business outside of the United States are also required to complete the Grants.gov registration process, in addition to fulfilling supplementary requirements for doing business with the U.S. Government.

If business is conducted with the Federal Government on a continuing basis, it is likely that some of the required actions have already been completed, e.g., obtaining a Data Universal Numbering System (DUNS) number or registration as an Entity in the System for Award Management

(SAM). Detailed information, links, automated tools, and checklists are available at https://www.grants.gov/web/grants/applicants/organization-registration.html.

The following steps are required as part of the Grants.gov registration process:

1. DUNS Number

The applicant organization and all subrecipient/subawardee organizations must have or obtain a DUNS number. A DUNS number is a unique identification number provided by the commercial company Dun & Bradstreet. If an organization does not have a DUNS number, an authorized business official of the organization can request one by calling 866-705-5711 or by registering online (https://fedgov.dnb.com/webform). Organizations located outside of the United States can request and register for a DUNS number online via web registration (https://fedgov.dnb.com/webform). Web registration can take 1-2 business days.

2. SAM Registry

The applicant organization must be registered as an entity in SAM (https://www.sam.gov) and receive confirmation of an "Active" status before submitting an application through Grants.gov. The SAM validates organization information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through electronic funds transfer. An organization must identify an Accounts Receivable point of contact (POC), an Electronic Business (E-Biz) POC, and a Government Business POC during the SAM registration process. ***Entity registrations in SAM have an annual expiration. Verify the status of your organization's Entity registration in SAM well in advance of the application submission deadline.*** An organization can register in SAM online at https://www.sam.gov/. If your organization does not have either an Employer Identification Number (EIN) or Tax Identification Number (TIN), allow at least 2 weeks to receive this information from the U.S. Internal Revenue Service. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination to direct the Federal award to a qualified applicant.

The General Services Administration (GSA) has implemented fraud prevention security measures in the SAM that require every ***new*** contractor registrant to provide a written (hard copy), notarized letter confirming that the entity's Administrator is authorized to register the entity in the SAM database or to make changes to its registration. Effective April 29, 2018, the notarized letter process is now mandatory on all ***current*** registrants at SAM who have a requirement to update data on their SAM record. The notarized letter is mandatory and is required before the GSA Federal Service Desk will activate the entity's registration. The Office of the Secretary of Defense and GSA realize the length of time needed to transmit, receive, process, and approve the notarized letters presents a significant impact on the ability of the contracting activity to make timely awards, but these steps must be taken to mitigate fraud concern. ***Notarized letters are required for all new and existing SAM-registered entities.*** The notarized letters must be postal service mailed (not emailed or faxed) to the "Federal Service Desk" and must contain the information outlined in the SAM-posted Frequently Asked

Questions (FAQs) at https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update. Instructions for domestic entities and instructions for international entities with embedded templates for use are also provided within the SAM Update notice with FAQs at https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update.

Additional information and step-by-step registration directions are detailed in the SAM User Guide and other GSA training materials in the Help area at https://www.sam.gov/.

Applications will be rejected by Grants.gov (1) if the organization's Entity registration in SAM is not active or (2) if during the SAM registration process, the organization did not answer "Yes" when asked "Do you want to be eligible for grants and other Federal assistance?"

3. Commercial and Government Entity (CAGE) Code

The applicant organization must have a CAGE Code. The Defense Logistics Information Service in Battle Creek, Michigan, is the only authorized source of CAGE Codes. CAGE Codes will be assigned to registrants as their SAM registration advances through the validation process. Foreign registrants in SAM must be assigned a North Atlantic Treaty Organization CAGE Code (NCAGE). An NCAGE code can be obtained by contacting the National Codification Bureau of the country where the organization is located or by visiting the website (https://cage.dla.mil/Request). On average, CAGE Code or NCAGE Code validation in SAM occurs within 3 business days after the TIN is validated.

4. Authorized Organizational Representative

Each organization must have an AOR who is registered with Grants.gov (individual PIs do not register with Grants.gov). An AOR must be a member of the Grants.gov Workspace grant team as the Business Official authorized to submit the completed Workspace application package. An organization's E-Biz POC must authorize an AOR. An individual may serve as both the E-Biz POC and the AOR. Before application submission, the AOR must be registered to submit on behalf of the organization at Grants.gov (https://apply07.grants.gov/apply/OrcRegister).

An AOR must first register with the Grants.gov credential provider at https://apply07.grants.gov/apply/OrcRegister to obtain a username and password. Once an AOR has completed the Grants.gov registration process, Grants.gov will notify the E-Biz POC of the registration. The E-Biz POC will then log in to Grants.gov and assign and authorize the appropriate roles, which may include the AOR role, thereby giving the AOR permission to complete and submit applications on behalf of the organization. When an E-Biz POC approves an AOR, Grants.gov will send the AOR a confirmation email.

At the time of application submission to Grants.gov, the AOR is certifying to the best of his/her knowledge that all information provided in the application is current, accurate, and complete.

For applications submitted through Grants.gov, the name of the AOR submitting the application is inserted into the application's signature line, serving as the electronic signature.

Individuals who make legally binding commitments on behalf of an organization must be authorized as AORs by the E-Biz POC. This step, often overlooked, is crucial for valid and timely submissions.

5. Grants.gov Workspace

Applicants must create a Grants.gov Workspace, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Once the Workspace has been created, participants (grant team members) can be added and the required forms can be completed and reviewed before submitting.

Each application submission must include the completed Grants.gov application package of forms associated with the specific Program Announcement in Grants.gov (https://www.grants.gov/).

Applicants who prepare the application outside Workspace must download the individual PDF forms from Grants.gov, complete and save the forms, and upload them to Workspace. A compatible and identical version of Adobe Reader must be used to view, complete, and submit an application package consisting of PDF forms if more than one person accesses the application package. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. ***Grants.gov will reject an application package that is opened at any time by an individual with an incompatible version of Adobe Reader.*** Rejected applications must be resubmitted using a new Grants.gov application package and a supported version of Adobe Reader prior to the application submission deadline. It is the applicant's responsibility to verify his/her Adobe Reader's compatibility with Grants.gov: https://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html. A no-cost compatible version of Adobe Reader can be downloaded at http://get.adobe.com/reader/otherversions/. All contributors to the application must use matching compatible versions of Adobe software when editing and preparing application components outside Workspace. The use of different software versions will result in corruption of the submitted file.

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

Any modifications to the Project Narrative or Budget Form require submission of a changed/ corrected Grants.gov application package to Grants.gov prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be modified during the application verification period.

The application submission deadline and the end of the application verification period in eBRAP are stated on the title page of the respective Program Announcement. See Section III.C, Applicant Verification of Grants.gov Submission in eBRAP, for additional details.

A. Grants.gov Application Package Components

1. SF424 (Research & Related), Application for Federal Assistance Form

All appropriate information must be entered into this form to allow for auto-population of subsequent forms in the Grants.gov application package.

- **Block 1 – Type of Submission.** For original submissions, select the "Application" box. For changes that must be made after the original submission, the complete Grants.gov application package must be resubmitted with the "Changed/Corrected Application" box selected.

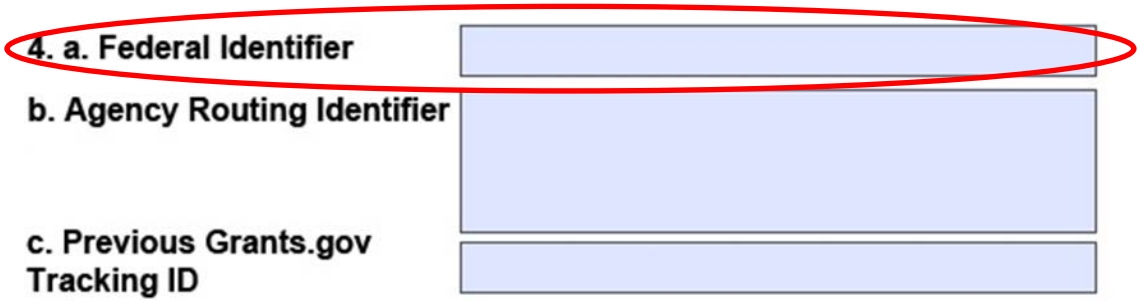
- **Block 2 – Date Submitted.** Enter the date the application is submitted.

    - **Applicant Identifier.** Enter the submitting organization's Control Number, if applicable. If there is no Organization Control Number, leave this field blank.

- **Block 3 – Date Received by State and State Application Identifier.** Not applicable.

- **Block 4a – Federal Identifier Box.** Enter in the eBRAP log number assigned during pre-application submission.

Figure 1. Enter the eBRAP log number in Block 4a.



- **Block 4b – Agency Routing Identifier.** Not applicable.

- **Block 4c – Previous Grants.gov Tracking ID.** For changed/correct applications, enter the Grants.gov Tracking Number for the original application.

- **Block 5 – Applicant Information.** Enter the information for the applicant organization. "Person to be contacted on matters involving this application" is the Business Official.

- **Block 6 – Employer Identification.** Enter the EIN or TIN as assigned by the Internal Revenue Service. If applying from an organization outside the United States, enter 44-4444444.

- **Block 7 – Type of Applicant.** Enter the information for the applicant organization.

- **Block 8 – Type of Application.** Select "New" for all submissions.

- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.

- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.

- **Block 11 – Descriptive Title of Applicant's Project.** Enter the same project title as used for the pre-application.

- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. Actual start and end dates will be determined during negotiations if the application is recommended for funding.

- **Block 13 – Congressional District of Applicant.** If the applicant organization is outside the United States, enter 00-000.

- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of the application. If outside the United States, select the appropriate country from the drop-down menu.

- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the project. These figures should match those provided in the Research & Related Budget.

- **Block 16 – Is Application Subject to Review by State Executive Order 12372 Process?** Select option b., "NO, program is not covered by E.O.12372."

- **Block 17 – Complete Certification.** Select the "I agree" box to provide the required certifications and assurances**.**

- **Block 18 – SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation.** If applicable, complete and attach Standard Form LLL (SFLLL) to disclose lobbying activities pursuant to Title 31 of United States Code, Section 1352 (31 USC 1352).

- **Block 19 – Authorized Representative.** Enter the contact information for the applicant organization's authorized representative. The "Signature of Authorized Representative" is automatically completed upon submission of the Grants.gov application package.

- **Block 20 – Pre-Application.** Not applicable.

- **Block 21 – Cover Letter Attachment.** Not applicable.

If a revised Project Narrative or Research & Related Budget Form document is needed, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID found in Block 4.c. of the SF424 Research & Related Form prior to the full application submission deadline.

2. Attachments Form

Grants.gov does not validate for the presence of attachments on the Attachments Form. Following retrieval and processing of the Grants.gov application, eBRAP will notify the

organizational representatives and PI by email to log into eBRAP to view, modify, and verify the Grants.gov 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. 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. See Section III.C, Applicant Verification of Grants.gov Submission in eBRAP, for additional details.

Each attachment in the Attachments Form must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 4. For all attachments, ensure that the file names are consistent with the guidance listed in the Program Announcement and below. Grants.gov will reject attachments with file names longer than 50 characters or incompatible file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire Grants.gov application package may not exceed 200 MB. Applicants must contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that a file exceeding the maximum size will be accepted.

For specific instructions regarding content and page limits of the Project Narrative, Supporting Documentation, and all other attachments to this Grants.gov form, refer to the Program Announcement.

All documents that require signatures must be signed. Both electronic and hand signatures will be accepted. Any document that is signed by hand should be scanned at a resolution of 100-150 dots per inch.

The following must be included as attachments:

Attachment 1: Project Narrative: Attach as a PDF file named "ProjectNarrative.pdf". The Project Narrative is the main body of the application. 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.

Submission of a Project Narrative that exceeds the page limit specified in the Program Announcement will result in administrative rejection of the application.

Attachment 2: Supporting Documentation: Combine and attach as a single PDF file named "Support.pdf". Include only supporting documentation as indicated in the Program Announcement. Submitting material that is not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed or the application may be administratively withdrawn.

All applications are provided fair and thorough reviews. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

For a list and descriptions of required supporting documents, refer to the Program Announcement.

Attachment 3: Technical Abstract: Attach as a PDF file named "TechAbs.pdf". Abstracts of all funded research projects will be posted on the CDMRP website at https://cdmrp.army.mil. 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.

The Technical Abstract will be posted publicly and will be included in the award agreement. Do not include proprietry information.

Attachment 4: Lay Abstract: Attach as a PDF file named "LayAbs.pdf". Abstracts of all funded research projects will be posted on the CDMRP website at https://cdmrp.army.mil. 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.

The Lay Abstract will be posted publicly. Do not include proprietry information.

Attachment 5: Statement of Work (SOW): Attach as a PDF file named "SOW.pdf". The SOW is an outline of specific aims of the proposed research project that establishes the project milestones during the performance period of the award. The SOW should contain sufficient detail to be informative as a stand-alone document. There is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit.

SOW Format: PIs are strongly encouraged to use the suggested SOW format stated in the Program Announcement. Templates for SOW formats are available on the eBRAP "Program Announcement & Forms" page (https://ebrap.org/eBRAP/public/Program.htm). The SOW must be in PDF format prior to attaching.

For specific instructions regarding SOW content, refer to the Program Announcement.

Attachments 6-15: Additional Documents (as applicable): Attach each as a separate PDF file, named as indicated in the Program Announcement (e.g., "Impact.pdf", "Innovation.pdf", "Training.pdf", "Transition.pdf").

For specific instructions regarding content, titles, and page limits for the Additional Documents, refer to the Program Announcement.

3. Research & Related Personal Data

This form will be used by DoD as the source of demographic information, such as gender, race, ethnicity, and disability information, for the Project Director (PD)/PI and all other persons identified as Co-PD(s)/Co-PI(s).

Each application must include this form with the name fields of the PD/PI and any Co-PD(s)/Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. If completing the form for multiple individuals, each Co-PD/Co-PI can be added by selecting the "Next Person" button. The demographic information, if provided, will be used for statistical purposes only and will not be made available to reviewers. Applicants who do not wish to provide some or all of the information should check or select the "Do not wish to provide" option.

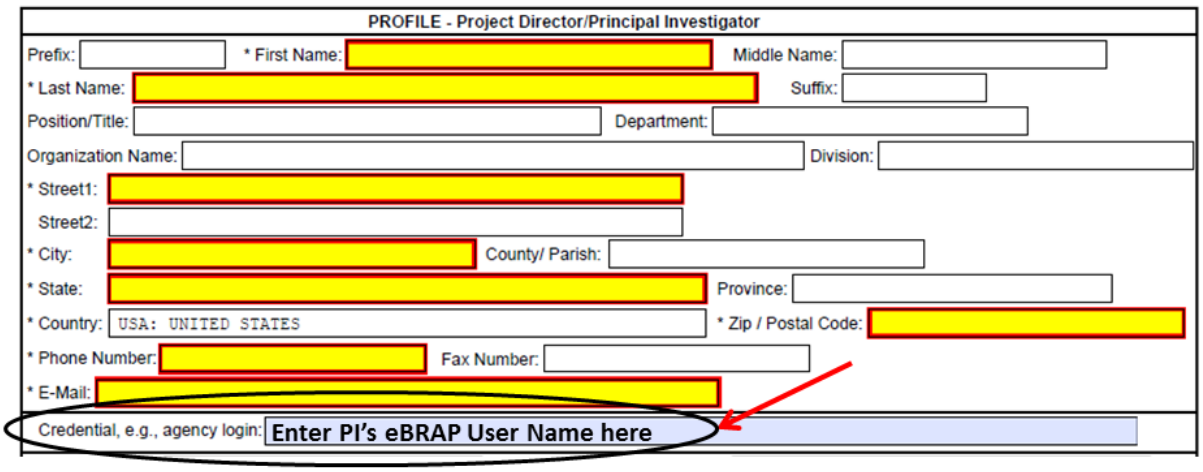
4. Research & Related Senior/Key Person Profile (Expanded)

The Degree Type and Degree Year fields on the Research & Related Senior/Key Person Profile (Expanded) form will be used by DoD as the source for career information. In addition to the required fields on the form, applicants must complete these two fields for all individuals that are identified as having the project role of PD/PI or Co-PD/Co-PI on the form. Additional senior/ key persons can be added by selecting the "Next Person" button.

Include the requested information for each person who will contribute significantly to the proposed research project.

In the "PROFILE – Project Director/Principal Investigator" section, enter the PI's User Name provided by eBRAP into the data field labeled "Credential, e.g., agency login" (Figure 2).

Figure 2. PI's eBRAP User Name



Biographical Sketch Suggested Format: The suggested biographical sketch format is available in a Microsoft Word document on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. Use of this document is optional.

The NIH Biographical Sketch may also be used. Each biographical sketch must be in PDF format prior to attachment. Page limitations will be specified in the Program Announcement.

- **PI Biographical Sketch:** This file must be titled "Biosketch_LastName.pdf" where "LastName" is the last name of the PI.

- **PI Previous/Current/Pending Support:** This file must be titled "Support_LastName.pdf" where "LastName" is the last name of the PI.

    - ***For all previous (award period of performance ending within the past 5 years), current, and pending research support,*** include the title, time commitments, supporting agency, name and address of the funding agency's procuring Contracting/Grants Officer, performance period, level of funding, brief description of the project's goals, and list of the specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.

    - If there is no previous, current, or pending support, enter "None." An updated previous, current, and pending support document will be required if an award is recommended for funding.

- **Key Personnel Biographical Sketches:** Each file must be titled "Biosketch_LastName.pdf" where "LastName" is the last name of the respective individual.

- **Key Personnel Previous/Current/Pending Support:** Each file must be titled "Support_LastName.pdf" where "LastName" is the last name of the respective individual. Refer to content requirements under "PI Previous/Current/Pending Support" listed above.

5. Research & Related Budget

An estimate of the total proposed research project cost, with a breakdown of all cost categories for each year, must be submitted on the Grants.gov Research & Related Budget Form. For limits on funding amounts, types of costs, and period of performance, refer to the Program Announcement. The budget and budget justification should include sufficient detail for the Government to determine whether the proposed costs are allowable, allocable, and reasonable for the proposed research. ***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.*** At the time of application submission to Grants.gov, the AOR is certifying to the best of his/her knowledge that all costs are current, accurate, and complete.

If the budget fails eBRAP validation 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.

No budget will be approved by the Government exceeding the cost limit stated in the specific Program Announcement or using an indirect rate exceeding the organization's negotiated rate.

Budget Regulations and Restrictions:

The following must be utilized in developing the budget:

- **Maximum Obligation:** Awards will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs. Foreign currency exchange rates for recipients performing research outside of the United States will be determined at the time of application submission.

- **Administrative and Cost Principles:** Recipients will be required to comply with the following, as applicable:

    - Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR 200), as implemented by Chapter XI of Title 2 CFR

    - Provisions of Chapter I, Subchapter C of Title 32, CFR, "DoD Grant and Agreement Regulations," Parts 26, 28, 37, and Title 2, CFR Part 1125

    - Federal Acquisition Regulation (FAR) Part 31

- **Pre-Award Costs:** An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the Government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award if such costs (1) are necessary to conduct the project and (2) would be allowable under the award, if awarded. If specific expenditures would otherwise require prior approval, the recipient must obtain the Grants Officer's approval before incurring the cost. Government prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new award.

    For-profit organizations must obtain the Grants Officer's approval prior to incurring any obligations and expenditures before the beginning date of the initial budget period of a new award.

    The incurrence of pre-award costs in anticipation of an award imposes no obligation on the Government either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred or in the absence of appropriations. The Government expects the recipient to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the organization's ability to accomplish the project objectives within the approved timeframe or in any way adversely affect the conduct of the project.

- **Cost of Preparing Applications:** The cost of preparing applications in response to a Program Announcement is not considered an allowable direct charge to any resultant award. However, the cost of preparing applications may be an allowable cost that can be included in the indirect/facilities and administrative cost as specified in the organization's applicable cost principles.

- **Currency:** All costs must be entered in U.S. dollars. Recipients performing research outside of the United States should include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used. Foreign currency exchange rates for recipients performing research outside of the United States will be determined at the time of application submission.

Submit a detailed budget and justification that covers the entire period of performance (not just the first year). The Government reserves the right to request a revised budget and budget justification and/or additional information.

Budget Instructions: Complete the Research & Related Budget Form following the instructions below. Begin by entering the organizational DUNS number, Budget Type, Name of Organization, and anticipated start and end dates. ***Ensure that the DUNS number is entered accurately or Grants.gov will reject the application.***

For all Federal agencies or organizations collaborating with Federal agencies applying to the Program Announcement, special restrictions apply to the budget and are described below.

For Federal Agencies: An application from a Federal agency must include in the budget justification a **Federal Financial Plan (Plan).** The Plan must address how all funds will be obligated before their period for obligation expires and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

For Collaborating Military Facilities: An application from an organization that includes collaboration with a Military Facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) must submit the DoD Military Budget Form(s) as instructed in Section 8, DoD Military Budget Form, below. The costs per year should be included on the Grants.gov Research & Related Budget form under subaward costs.

Section A: Senior/Key Person

- **Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be included on the Research & Related Subaward Budget Attachment(s) Form. Consultant costs should be listed under Section F.3 of the Research & Related Budget Form (Other Direct Costs, Consultant Services).

- **Base Salary:** Enter the current annual base salary (based on a full-time appointment) for each individual listed for the proposed research project. Establish labor costs using current labor rates or salaries. Labor rates or salaries may not be increased as a result of receiving an award. Identify and explain in the budget justification any proposed adjustments to rates or salaries. Any proposed increases in rates or salaries over the period of the award must be consistent with the applicable cost principles and organization's estimating procedures. ***For most Federal agencies, funding cannot be applied toward Federal salaries and therefore these salaries should not be included in the requested budget.***

- **Calendar, Academic, and Summer Months:** For each senior/key person, including unpaid personnel, list the number of months to be devoted to the proposed research project in the appropriate box.

- **Requested Salary:** Enter the amount of salary requested for this budget period.

- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the application is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement, other Federally approved rate agreement, or other policy document).

- **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.

- **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.

Section B: Other Personnel

- **Number of Personnel:** For each project role category, indicate the number of personnel for the proposed research project, including unpaid personnel.

- **Project Role:** Identify each project role category. Within the budget justification, describe the specific functions of the personnel in each project role.

- **Calendar, Academic, and Summer Months:** For each project role category, list the number of months to be devoted to the proposed research project in the appropriate box.

- **Requested Salary:** Enter the amount of salary requested for this budget period. ***For most Federal agencies, funding cannot be applied toward Federal salaries and therefore these salaries should not be included in the requested budget.***

- **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the application is recommended for funding, the organization will be required to provide documentation to support the

fringe benefits (e.g., the current DHHS Rate Agreement, other Federally approved rate agreement, or other policy document).

- **Funds Requested:** Enter the total funds requested for each project role category listed for the proposed research project.

Section C: Equipment Description. Equipment is tangible personal property (including information technology systems) having a useful life of more than 1 year and a per unit acquisition cost that equals or exceeds the lesser of (a) $5,000 or (b) the recipient's or the subrecipient's capitalization threshold for financial statement purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project. If equipment is requested, provide a detailed list showing the cost of each item. The budget justification for any requested equipment must describe, as applicable:

- Special test equipment to be fabricated for specific research purposes and its cost.

- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.

- Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the recipient with recipient funds, would be capitalized for Federal income tax purposes.

In addition, requests for equipment must include a rationale for estimated costs.

Section D: Travel. Travel costs may include:

- Costs to attend scientific/technical meetings per year as specified in the Program Announcement: Include the meeting name, purpose, location, and date, if known, in the budget justification. International travel may be requested but must be justified with additional documentation and is subject to approval by the Grants Officer.

- Costs for travel associated with the execution of the proposed work (if applicable): Reasonable costs for travel between collaborating organizations should be included. International travel may be requested but must be justified with additional documentation and is subject to approval by the Grants Officer.

- Costs to attend required meetings (if applicable): Include the meeting name if identified in the Program Announcement and a statement in the budget justification confirming that the PI will attend the required meeting.

- Funds to an extramural organization may not be used to cover travel costs for DoD military and civilian employees. All approved travel costs for DoD military and civilian employees will be paid by the Government through a direct fund transfer. Proposed travel costs for DoD military and civilian employees should be included on the DoD Military Budget Form.

Section E: Participant/Trainee Support Costs. Enter the funds requested for tuition/fees, health insurance, stipends, travel, subsistence, and other costs.

Section F: Other Direct Costs

- **Materials and Supplies:** Supplies means all tangible personal property, including a computing device, acquired under an award that does not meet the definition of equipment. The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies for each year. For individual or total materials and supplies costing $5,000 or more per year, provide additional breakdown. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description.

    - If a computer/software purchase is requested, include the following in the budget justification:

        - Detailed explanation for why purchase of computer/software is required to complete the proposed research project.

        - Statement verifying that the requested computer/software is not currently available for use by the PI.

- **Publication Costs:** Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.

- **Consultant Services:** Whether or not funds are requested, include in the budget justification the names and organizational affiliations of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

- **Automated Data Processing (ADP)/Computer Services:** Include the cost of computer services, including computer-based retrieval of scientific, technical, and education information. Include in the budget justification the provider's computer service rates. See the "Materials and Supplies" bullet above regarding the purchase of computers.

- **Subaward/Consortium/Contractual Costs:** Include the total funds requested for (1) all subaward/consortium organization(s) proposed for the research project and (2) any other contractual costs proposed for the research project. This amount should be supported in the subaward/consortium/contractual costs provided in the R & R Subaward Budget Attachment(s) Form.

  If a Military Facility (Military Health System 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 & Related Budget form under subaward costs.

All direct and indirect costs of any subaward must be included in the direct costs of the primary award. No budget will be approved by the Government exceeding the cost limit stated in the Program Announcement or using an indirect rate exceeding the organization's negotiated rate.

- **Equipment or Facility Rental/User Fees:** List proposed equipment or facility rental/user fees. Include appropriate information (hours and rates) in the budget justification.

- **Alterations and Renovations:** Alteration and renovation (A&R) costs can be requested if the costs are essential to accomplish the objectives of the research project and are a minor portion of the overall budget. A description of the existing facility and detailed description of the requested changes, along with a cost estimate, must be included in the budget justification. Costs for the construction of facilities are not allowable.

- **Other Expenses:** Itemize other anticipated direct costs such as communication costs and organizationally provided services. These items should be described in detail and clearly justified in the budget justification. Organizationally provided services should be supported by the organization's current cost/rate schedule.

  Include itemized research-related subject costs for the proposed research project. These costs are strictly limited to expenses specifically associated with the proposed research project.

Section G: Direct Costs. Include the total direct costs (A-F).

Section H: Indirect Costs. The indirect costs category may include Facilities and Administrative (F&A) costs, overhead, General and Administrative (G&A), and other. The most recent Federal agency approved rate(s) should be applied. If the rate(s) has been approved by other than a Federal agency, indicate the source of the approval.

In accordance with 2 CFR 200.414, a non-Federal entity that has never received a negotiated indirect cost rate may elect to charge a de minimis rate of 10% of modified total direct costs. Costs must be consistently charged as either indirect or direct costs, but may not be double-charged or inconsistently charged as both. If this methodology is chosen, it must be used consistently for all Federal awards until such time as the non-Federal entity chooses to negotiate for a rate.

Provide details of the direct cost base (modified total direct costs, salary and wage, or other). Identify any costs that have been excluded from the base (in accordance with the approved rate agreement). Also indicate if the rate(s) is an on-site or off-site rate(s). If more than one rate is applicable, provide a breakdown of the calculation.

Provide documentation to support the indirect cost rate (e.g., the current DHHS Rate Agreement, other Federally approved rate agreement, or other policy document) via eBRAP (https://eBRAP.org).

Organizations can also visit the DHHS (https://rates.psc.gov/fms/dca/negotiations.html), the Office of Naval Research (https://www.onr.navy.mil/Contracts-Grants/manage-grant/indirect-cost-proposal.aspx), and the Defense Contract Audit Agency (https://www.dcaa.mil/) for additional information on indirect rates.

Section I: Total Direct and Indirect Costs. Include total costs for the proposed research project.

Section J: Fee. Charging a fee or profit to an assistance agreement, either by the recipient/awardee or subrecipient/subawardee, is prohibited.

Section K: Budget Justification. Provide a clear budget justification for each item in the budget over the entire period of performance and attach as a single PDF file to Section K of the Research & Related Budget.

Applications from **Federal agencies** must include in their budget justifications a **Federal Financial Plan (Plan).** The Plan must address how all funds will be obligated before their expiration for obligation, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

Organizations must provide sufficient detail and justification so the Government can determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

6. Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. Add more sites as necessary using the "Next Site" button. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach it to this form. Each additional research site requesting funds will require a subaward budget.

7. Research & Related Subaward Budget Attachment(s) Form (if applicable)

Complete a separate detailed Research & Related Budget including a budget justification for each subaward (subgrant or contract) in accordance with the instructions listed above. Title each individual subaward, "Research & Related Budget," with the name of the subawardee/ subrecipient organization, and attach to the Research & Related Subaward Budget Attachment(s) Form.

All direct and indirect costs of any subaward must be included in the direct costs of the primary award. The primary award (including the direct and indirect costs of any subawardees) will not exceed the cost limit stated in the Program Announcement.

A description of services or materials that are to be provided under the subaward is required. Organizations must provide sufficient detail and justification so that the Government can determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

8. DoD Military Budget Form

This section addresses requirements and procedures when a Military Facility will be a collaborator in performance of an extramural project.

Budget Form: Complete a separate **"DoD Military Budget Form"** for each Military Facility involved in the project. The form is available for download on the eBRAP "Funding Opportunities and Forms web page (https://eBRAP.org). Do not complete the Grants.gov Research & Related Subaward Budget Attachment Form.

Direct Costs:

- **Salaries:** Include the positions/titles/ranks and levels of effort of all DoD civilian and military personnel expected to work on the extramural project, whether or not salaries/fringe benefits are proposed. Salaries/fringe benefits may be reimbursed, either directly by the Federal Government to the facility or through the extramural award to the facility, but only under certain limited circumstances, which will be discussed during negotiations. Extramural organizations may provide personnel to work at intramural DoD partnering organizations. The Extramural personnel costs should not be included here but on each organization's Research & Related Budget Form (Sections A and B).

- **Travel:** Include costs to be incurred by DoD civilian and military personnel. However, these costs cannot be reimbursed through the extramural award. All approved travel costs of DoD military and civilian employees will be paid by the Government through a direct fund transfer. Some restrictions apply. Processes will be discussed during negotiations.

- **Consultants, Equipment, Materials, Supplies, Other, Etc.:** Include all anticipated direct costs. The Military Facility should consider whether the applicant organization can purchase the items/resources and provide them to the facility. The organization may provide resources to the Military Facility, such as consultants, supplies, equipment, etc., acquired with award funds. If this is feasible, these funds should not be included on the applicant organization's Research & Related Budget Form and should not be included on this form.

- **Rates/Fees (Other than Indirect Cost Rates and Profit):** Where there are no DoD-established reimbursement rates (e.g., Institutional Review Board [IRB] fees, Institutional Animal Care and Use Committee [IACUC] fees), the Military Facility's

Resource Manager (RM)/Comptroller/Task Area Manager or equivalent Business Official must provide details of how the proposed rates/fees were determined. Rates/fees should be included in the Other Direct Costs line of the Research & Related Budget Form (Section F.8-10).

- **Indirect Costs:** If an indirect cost rate is proposed, include documentation to support the rate (i.e., cost pool(s) and what items are included in each pool). The Military Facility should consult with its RM office (or equivalent) for assistance in determining a rate.

- **Total Costs:** Include the facility's combined direct and indirect costs. Enter the total here and also include it in the Subaward/Consortium/Contractual Costs budget line on the Research & Related Budget Form (Section F.5 of the form.).

Budget Justification: Include a budget justification for each year, for each Military Facility. A description of services or materials that are to be provided by the collaborating Military Facility is required. The Military Facility researcher(s) should coordinate with his/her local RM office (or equivalent) to prepare a sound budget and justification for the estimated costs. Applicant organizations must provide sufficient detail and justification to enable the Federal Government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort. In addition, the Military Facilities' direct and indirect costs to be supported when performing collaborative research with the extramural organization must meet the requirements of the DoD's Financial Management Regulation (FMR) 7000.14-R.

Direct Fund by Federal Agency: If possible, the USAMRMC's RM office will "direct fund" (via a Funding Authorization Document [FAD], Military Interdepartmental Purchase Request [MIPR], or other authorized method) the collaborating Military Facility to support all costs to be incurred in performance of the Military Facility's portion of the research project. When direct funded, these funds **will not** be included in the award amount to the contractor or recipient.

Funds Obligated on Extramural Award: If extraordinary circumstances exist whereby the USAMRMC RM office is not able to "direct fund" the Military Facility, the funds may be placed on the award and the contractor or recipient may provide award funds to the Military Facility. If known at the time of submission, the Military Facility, in conjunction with the applicant organization, should provide a written justification for this funding method. Suggested areas to address are the research-related activities that will take place at the Military Facility and the associated costs, when the activities will take place, why "direct funding" is not possible, why the applicant organization cannot provide the necessary resources and/or services, the Comptroller's (or equivalent) ability to accept and process award funds appropriately, etc.

Prior to the issuance of any award utilizing the funding method described above, written approval from the U.S. Army Medical Research Acquisition Activity's (USAMRAA's) Principal Assistant Responsible for Contracting (PARC) will be required. PARC approval is not required at the time of submission. The justification will be considered by the USAMRAA Grants Officer in consultation with the applicant organization and the Contracting Officer's Representative/ Grants Officer's Representative. If considered to be justified, the Contracting/Grants Officer will seek PARC approval.

Technology Transfer: The Military Facility researcher(s) should also coordinate with his/her technology transfer office, when applicable. The facility may require that a cooperative research and development agreement (CRADA) or other instrument (as authorized by law or regulation) be executed between the facility and the contractor or recipient before work between the organization can begin or funds can be provided to the Military Facility. The CRADA (or other instrument) is not required at the time of application submission. A timeline for execution of the document will be established during negotiations.

B. Submission to Grants.gov

Grants.gov recommends submitting the application package at least 24-48 hours prior to the close date to provide time to correct any potential technical issues that may disrupt the application submission.

All applications must be received by the deadline indicated on the title page of the respective Program Announcement. Proof of timely submission is automatically recorded by Grants.gov. An electronic date/time stamp is generated within the system when the application is successfully received by Grants.gov. The applicant AOR will receive an acknowledgement of receipt and a Tracking Number (GRANTXXXXXXXX) from Grants.gov with the successful transmission of their application. Applicant AORs will also receive the official date/time stamp and Grants.gov Tracking Number in an email serving as proof of their timely submission.

C. Applicant Verification of Grants.gov Submission in eBRAP

The full application package submitted to Grants.gov may be viewed in eBRAP until the end of the application verification period. After eBRAP has processed the full application, PIs will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Research & Related Budget Form,*** may be modified. See the Program Announcement for specific full application submission and application verification deadlines.

Specific information must be identical between the pre-application and the full application for eBRAP to process an application. The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP.

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement 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 Research & Related Budget fails eBRAP validation or if the Project Narrative or the Research & Related Budget need to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. The full application submission deadline and the end of the application verification period in eBRAP are stated in the specific Program Announcement.

D. Application Tracking

After a Workspace package has been successfully submitted, a Grants.gov Tracking Number (GRANTXXXXXXXX) is automatically assigned to the package. The number will be listed on the Confirmation page that is generated after submission. The submission of a Workspace package can be tracked from the Workspace or by visiting Grants.gov (https://www.grants.gov/web/grants/applicants/track-my-application.html) and entering the Tracking Number.

IV. APPLICATION SUBMISSION FOR INTRAMURAL ORGANIZATIONS

A. eBRAP Application Package Components

The eBRAP application package includes the following components, which are organized in eBRAP by separate tabs. **To access these tabs, go to "My Applications" and click on "Start Full Application"** for the log number under which the pre-application was submitted.

- **Tab 1 – Summary:** Provides a summary of the application information.
- **Tab 2 – Application Contacts:** This tab will be populated by eBRAP. Add the AOR.
- **Tab 3 – Full Application Files:** Under each Application Component in eBRAP, upload each as an individual PDF file. Refer to Appendix 4 for detailed formatting guidelines.

1. **Application Component – Attachments:** Each attachment must be uploaded as an individual PDF file unless otherwise stated. Specific page limits are noted in the Program Announcement.

   Attachment 1: Project Narrative (XX-page limit): Attach as a single PDF file named "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.

   Submission of a Project Narrative that exceeds the page limit specified in the Program Announcement will result in administrative rejection of the application.

Attachment 2: Supporting Documentation: Combine and attach as a single PDF file named "Support.pdf". Include only supporting documentation as indicated in the Program Announcement. Submitting material that is not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed or the application may be administratively withdrawn.

All applications are provided fair and thorough reviews. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

For a list and descriptions of required supporting documents, refer to the Program Announcement.

Attachment 3: Technical Abstract: Attach as a single PDF file named "TechAbs.pdf". Abstracts of all funded research projects will be posted on the CDMRP website at https://cdmrp.army.mil. 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.

The Technical Abstract will be posted publicly and will be included in the award agreement. Do not include proprietry information.

Attachment 4: Lay Abstract: Attach as a PDF file named "LayAbs.pdf". Abstracts of all funded research projects will be posted on the CDMRP website at https://cdmrp.army.mil/. 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.

The Lay Abstract will be posted publicly. Do not include proprietry information.

Attachment 5: Statement of Work: Attach as a PDF file named "SOW.pdf". The SOW is an outline of specific aims of the proposed research project that establishes the project milestones during the performance period of the award. The SOW should contain sufficient detail to be informative as a stand-alone document. There is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit.

SOW Format: PIs are strongly encouraged to use the suggested SOW format stated in the Program Announcement. Templates for SOW formats are available on the eBRAP "Program Announcement & Forms" page (https://ebrap.org/eBRAP/public/Program.htm). The SOW must be in PDF format prior to attaching.

For specific instructions regarding SOW content, refer to the Program Announcement.

Attachments 6-15: Additional Documents (as applicable): Attach each as a separate PDF file, named as indicated in the Program Announcement (e.g., "Impact.pdf", "Innovation.pdf", "Training.pdf", "Transition.pdf").

For specific instructions regarding content, titles, and page limits for the Additional Documents, refer to the Program Announcement.

2. **Research & Related Personal Data Form:** This form will be used by DoD as the source of demographic information, such as gender, race, ethnicity, and disability information, for the PD/PI and all other persons identified as Co-PD(s)/Co-PI(s).

   Each application must include this form with the name fields of the PD/PI and any Co-PD(s)/Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. If completing the form for multiple individuals, each Co-PD/Co-PI can be added by selecting the "Next Person" button. The demographic information, if provided, will be used for statistical purposes only and will not be made available to merit reviewers. Applicants who do not wish to provide some or all of the information should check or select the "Do not wish to provide" option.

   Upload the Research & Related Personal Data Form as "PersonalData_LastName.pdf" under the Key Personnel Application Components.

3. **Application Component - Research & Related Senior/Key Person Profile**

   Each attachment must be uploaded as an individual PDF file unless otherwise stated. The Biographical Sketches and the Previous/Current/Pending Support for the PI and Key Personnel may be either attached to the Research & Related Senior/Key Person Profile (Expanded) Form or uploaded as individual files in the "Key Personnel" Application Component.

   Research & Related Senior/Key Person Profile (Expanded) Form: The Degree Type and Degree Year fields on the Research and Related Senior/Key Person Profile (Expanded) form will be used by DoD as the source for career information. In addition to the required fields on the form, applicants must complete these two fields for all individuals that are identified as having the project role of PD/PI or Co-PD/Co-PI on the form. Additional senior/key persons can be added by selecting the "Next Person" button.

   Upload the Research & Related Senior/Key Person Profile (Expanded) form as "KeyPersonnel_LastName.pdf" under the Key Personnel Application Components.

   Include the requested information for each person who will contribute significantly to the proposed research project.

   Biographical Sketch Suggested Format: The suggested biographical sketch format is available in a Microsoft Word document on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. Use of this document is optional. The NIH Biographical Sketch may also be used. Each biographical sketch must be in PDF format prior to attachment. Page limitations will be notated in the Program Announcement.

   - **PI Biographical Sketch:** This file must be titled "Biosketch_LastName.pdf" where "LastName" is the last name of the PI.

- **PI Previous/Current/Pending Support:** This file must be titled "Support_LastName.pdf" where "LastName" is the last name of the PI.

    - ***For all previous (award period of performance ending within the past 5 years), current, and pending research support, include*** the title, time commitments, supporting agency, name and address of the funding agency's procuring Contracting/Grants Officer, performance period, level of funding, brief description of the project's goals, and list of the specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.

    - If there is no previous, current, or pending support, enter "None." An updated previous, current, and pending support document will be required if an award is recommended for funding.

- **Key Personnel Biographical Sketches:** Each file must be titled "Biosketch_LastName.pdf" where "LastName" is the last name of the respective individual.

- **Key Personnel Previous/Current/Pending Support:** Each file must be titled "Support_LastName.pdf" where "LastName" is the last name of the respective individual. Refer to content requirements under "PI Previous/Current/Pending Support" listed above.

4. **Application Component – Budget Form:** Complete the DoD Military Budget Form and Justification. Begin by entering the PI name, eBRAP Log number, and period of performance fields at the top of the DoD Military Budget Form. **DoD Civilian and Military Personnel:** Personnel involved in the project should be listed in this section; however, this award is not intended to provide salary support for any Federal employee, as those costs were to have been included in infrastructure costs. If salary support is requested, sufficient justification must be provided in the budget justification section.

    DoD Military Budget Form Instructions:

    - **Name:** Beginning with the PI, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, mentor (if applicable), and support staff.

    - **Role on Project:** Identify the role of each participant listed. Describe his/her specific functions in the proposed research in the budget justification.

    - **Type of Appointment (Months):** List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The Government assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time (e.g., 50%), note this with an asterisk (*) and provide a full explanation in the budget justification. Individuals may

have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

- **Annual Base Salary:** Enter the annual organizational base salary (based on a full-time appointment) for each individual listed for the project.

- **Effort on Project:** List the percentage of each appointment to be spent on this project for all staff members including unpaid personnel.

- **Salary Requested:** Enter the salary for each position for which funds are requested. This is calculated automatically from the data provided. If you do not wish this to be calculated for you, uncheck the small "Calculate Salary" checkbox in the bottom of the field. Calculate the salary request by multiplying an individual's organizational base salary by the percentage of effort on the project.

- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines.

- **Totals:** Calculated automatically from the data provided.

- **Major Equipment:** Provide an itemized list of proposed equipment, showing the cost of each item. Equipment is any article of nonexpendable tangible property having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit.

- **Materials, Supplies, and Consumables:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies.

- **Travel Costs:** PIs are responsible for budgeting for all costs associated with travel, including airfare, hotel, etc., associated with the trip. Anticipated travel costs should be built into the budget at current or projected DoD per diem rates. Travel costs may include:

    - Travel costs for the PI to attend the required In-Progress Review meeting each year.

    - Travel costs for up to one investigator to travel to one scientific/technical meeting per year.

    - Travel costs between collaborating organizations.

- **Research-Related Subject Costs:** Include itemized costs of subject participation in the proposed research. These costs are strictly limited to expenses specifically associated with the proposed research.

- **Other Direct Costs:** Itemize other anticipated direct costs such as publication and report costs, equipment rental (provide hours and rates), communication costs, and organizationally provided services. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results,

including direct charges for clerical services, illustrations, reprints, and distribution. Organizationally provided services should be supported by the organization's current cost/rate schedule. These items should be described in detail and clearly justified.

- **Contract Costs (Partnership/Collaboration Costs):** Should an intramural organization propose collaboration with an extramural entity for part of the research effort, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through the agency's procedures. **All direct and indirect costs of any partnership/ collaboration costs must be included in the total direct costs of the primary award**. The nature of the partnership/collaboration should be described in the Budget Justification section.

- **Total Direct Costs:** Calculated automatically from the data provided for the initial budget period on page F-2 and for the entire proposed period of support on page F-3.

- **Total Indirect Costs:** If funds for indirect costs are requested, sufficient justification must be provided in the budget justification section. The Government reserves the right to disallow any indirect costs not sufficiently justified. All direct and indirect costs of any proposed collaborator must be included in the total direct costs of the primary award. Refer to Section II.D.5, Funding Restrictions, of the Program Announcement for detailed information.

- **Total Costs:** This section is calculated automatically from the data provided.

- **Fee:** A profit or fixed fee is not allowable on awards or on subawards.

  ***Budget Justification Instructions*:** Provide a clear budget justification for each item in the budget over the entire period of performance in the Justification section of the DoD Military Budget Form. Itemize direct costs within each budget category for additional years of support requested beyond year one.

- **Federal Agency Financial Plan (required):** Provide a detailed Federal Agency Financial Plan after the budget justification information in the DoD Military Budget Form. The plan delineates how all FY19 funding will be obligated by **September 30, 2020**. The plan must include the funding mechanism(s) or contractual arrangements that will be used to carry over funds between fiscal years, if applicable. Any FY19 funding not obligated by September 30, 2020 may be withdrawn by the issuing Comptroller.

5. Application Component: Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. Add more sites as necessary using the "Next Site" button. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach it to this form. Each additional research site requesting funds will require a subaward budget.

- **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.

- **Tab 5 – Submit/Request Approval Full Application**

  Once all components have been 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 validate files against the Program Announcement requirements, and discrepancies will be noted. If no discrepancies are noted, press the "Confirm Submission" button to complete the application submission. eBRAP will notify your RM/Comptroller/Task Area Manager or equivalent Business Official by email to log into eBRAP to review and approve the full application package prior to the approval deadline.

  The full application package submitted to eBRAP may be viewed in eBRAP until the end of the application verification period. After eBRAP has processed the full application, PIs will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Research & Related Budget Form,*** may be modified. Modifications to application components may only be made after the Business Official has set the status to "Return to PI" for the PI to make changes, or "Draft" for the Business Official to make changes. See the Program Announcement for specific full application submission and application verification deadlines.

  Specific information must be identical between the pre-application and the full application for eBRAP to process an application. The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP.

APPENDIX 1

REGULATORY REQUIREMENTS

A. Safety and Environmental Requirements

Based on changes to DoD compliance requirements (Department of the Army Pamphlet [DA PAM] 385-69, DA PAM 385-10, 32 CFR 651, September 6, 2012), provisions previously required for Safety and Environmental Compliance have been removed. However, in certain instances, compliance review may require submission of additional documentation prior to the awarding of any assistance agreement. Such instances may include use of Army-provided infectious agents or toxins, Biological Select Agents or Toxins, specific chemical agent(s), or pesticides outside of an established laboratory. The USAMRMC Office of Surety and Environment will identify any need for compliance review and documents must be submitted upon request.

Additional information is available at:
https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.environmental

B. Research Protections Review Requirements – Use of Human Subjects, Human Anatomical Substances, Human Subject Data, Human Cadavers, and Animals

The USAMRMC Office of Research Protections (ORP) ensures that research conducted, contracted, sponsored, supported, or managed by the DoD and involving human subjects, human anatomical substances, human subject data, human cadavers, and animals are conducted in accordance with Federal, DoD, Army, USAMRMC, and international regulatory requirements.

PIs and applicant organizations **may not commence performance** of research involving the above, **or expend funding** on such efforts, until regulatory documents are submitted and approved by the USAMRMC ORP to ensure that DoD regulations are met. All expectations described below are consistent with the DoD Instruction (DoDI) 3216.01, "Use of Animals in DoD Programs," as issued September 13, 2010, available at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations and DoDI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," as issued on November 8, 2011, and available at https://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

The ORP Animal Care and Use Review Office (ACURO) is responsible for administrative review, approval, and oversight of all animal research protocols, including all changes made during the life of the protocol.

The ORP Human Research Protection Office (HRPO) is responsible for administrative review, approval, and oversight of research involving human subjects, human anatomical substances or data, and the use of human cadavers (including specimens obtained postmortem). A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

1. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO, a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. All amendments or modifications must also be reviewed prior to initiation for the life of the award. 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." For guidance on which version of the appendix to use, as well as links to both, visit the ACURO website at: https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_Animal appendix. ***Allow at least 2 to 3 months for regulatory review and approval processes for animal studies.***

For additional information, send questions via email to ACURO (usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil).

2. Use of Human Cadavers or Human Anatomical Substances Obtained from Human Cadavers

Research, development, test and evaluation (RDT&E), education or training activities involving human cadavers or human anatomical substances obtained from cadavers shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, April 20 2012 (https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview). The USAMRMC ORP is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this Army policy. **HRPO must review the use of cadavers, including postmortem specimens, for compliance with the Army Cadaver Use Policy. Additional requirements apply to activities involving exposure of cadavers to impacts, blasts, ballistics testing, crash testing, and other destructive forces.**

Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Specific requirements for submission and review of RDT&E, education, and training involving cadavers and postmortem specimens can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

Written approvals to begin the activity will be issued under separate notification to the recipient. Questions regarding submission of human cadaver research for USAMRMC ORP review and approval should be directed to the ORP at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

3. Research Involving the Secondary Use of Data/Specimens

Research involving the use of human data and/or specimens not otherwise subject to institutional review requires a determination letter (e.g., stating that the project does not constitute "human subjects research" or can be considered "exempt human subjects research") from the PI's human subjects protection office as well as a concurrence from the ORP HRPO at USAMRMC.

All USAMRMC-supported research involving the secondary use of human data, records, human tissue, or human specimens (hereafter referred to as data/specimens) must be reviewed for compliance with Federal and DoD human subjects protection requirements and approved by the ORP prior to implementation. USAMRMC ORP HRPO review includes assessing the source of the data/specimens and whether the initial manner and consent for the data/specimen collection permits use in the DoD-funded research protocol. HRPO review, approvals, and determinations for specimen research are based upon the nature of the research, the source of the data/specimens, use and/or disclosure of identifiable health information, privacy and confidentiality protections, and whether the individual providing the data/specimens allowed the use of his/her data/specimens for research.

NOTE: The protocol submitted for HRPO review should include only those activities funded by the DoD, as referenced in the SOW. If the DoD-funded activities have been added to an ongoing/existing protocol that is not DoD-funded, the HRPO will require the PI to write a stand-alone protocol that is limited to those activities supported under the DoD award.

For additional guidance and instructions on HRPO review of any DoD-funded research activities involving access, use, and analysis of data/specimens, investigators should submit the HRPO Submission Form for Secondary research found on the ORP HRPO website. https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo.

4. Research Involving Human Subjects

In addition to local IRB review, investigators must submit all USAMRMC-funded research protocols involving human subjects for review and approval by the USAMRMC ORP HRPO prior to implementation of the research. The focus of this review is to validate the IRB review as appropriate and ensure that DoD, Army, and USAMRMC regulatory requirements have been met.

Questions regarding applicable human subjects protection regulations, policies, and guidance should be directed to the local IRB, the ORP HRPO (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), and/or the U.S. Food and Drug Administration (FDA) as appropriate. For in-depth information and to access HRPO protocol submission forms, refer to the ORP HRPO website (https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo).

ORP HRPO-required language must be inserted into the consent form, and compliance with DoD regulations may require that additional information be included in the protocol.

The ORP HRPO ensures that DoD-supported and/or -conducted research complies with specific DoD laws and requirements governing research involving human subjects. These laws and requirements may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already-approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators

carefully read "Information for Investigators" at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo. The time to approval depends greatly on adherence to the requirements described within. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission.

Documents related to the use of human subjects or human anatomical substances will be requested if the application is recommended for funding. ***Allow at least 2 to 3 months for regulatory review and approval processes for studies involving human subjects.***

Specific requirements for HRPO submission and review of research involving human subjects can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

(1) Assurance of Compliance: Each institution engaged in non-exempt human subjects research must have a current DHHS Office for Human Research Protection Federalwide Assurance or DoD Assurance.

(2) Training: Personnel involved in human subjects research must have completed appropriate training in the protection of human subjects per institutional requirements. Documentation confirming completion of appropriate training may be required during the regulatory review process.

(3) Informed Consent Form: The following must appear in the consent form:

- A statement that the DoD is providing funding for the study.
- A statement that representatives of the DoD are authorized to review research records.
- In the event that Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DoD must be listed as one of the parties to whom private health information may be disclosed.

(4) Intent to Benefit: The requirements of 10 USC 980, which are applicable to DoD-sponsored research, must be considered. 10 USC 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an *experimental subject* unless (1) the informed consent of the subject is obtained ***in advance***; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative for the subject."

An individual not legally competent to provide informed consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled as an ***experimental subject*** in a DoD-supported study unless the research is intended to benefit each subject enrolled in the study, including subjects enrolled in study placebo arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements. Note that the definition of ***experimental subject*** as defined in DoDI 3216.02 is a much narrower definition of ***human subject***. Research with

experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.

10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, studies that involve only blood draws, and tissue collections. Contact the HRPO at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil if further clarification regarding applicability of 10 USC 980 to the proposed research project is required.

Research Monitor Requirement: ***For research determined to be greater than minimal risk, DoDI 3216.02 requires that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol.*** The IRB must approve a written summary of the monitor's duties, authorities, and responsibilities.

The research monitor's duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report his/her observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI's institution. Research monitor functions may include:

- Observing recruitment and enrollment procedures and the consent process for individuals, groups or units;
- Overseeing study interventions and interactions;
- Reviewing monitoring plans and Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) reports; and/or
- Overseeing data matching, data collection, and analysis.

There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. At a minimum, the research monitor:

- May discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- Shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and
- Shall have the responsibility for promptly reporting his or her observations and findings to the IRB or other designated official and the HRPO.

A curriculum vitae or biographical sketch and documentation of human subjects protection training for the research monitor must be provided. There should be no apparent COI, and the research monitor cannot be under the supervision of the PI, other investigators, or research staff

associated with the proposed research project. If the duties of the research monitor could require disclosure of subjects' Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI's institution may require the identity and location of the research monitor to be described in the study HIPAA authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

1. **Military Personnel Volunteers:** The following is important information for research projects proposing to include military personnel as volunteers.

    - **Recruitment of Military Personnel:** Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator familiar with Service-specific requirements.

      A letter of support from Commanders of military units in which recruitment will occur or the study will be conducted will be requested by the HRPO. Some military sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

      Special consideration must be given to the recruitment process for military personnel. The Chain of Command must not be involved in the recruitment of military personnel and cannot encourage or order Service members to participate in a research study.

      For greater than minimal risk research, an ombudsman must be employed when conducting group briefings with active duty personnel to ensure that volunteers understand that participation is voluntary; this ombudsman may be recommended in other situations as well, especially when young enlisted Service members, who by virtue of their age and enlistment status are trained to follow orders, are being recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized, if possible.

    - **Payment to Federal Employees and Military Personnel:** Under 24 USC 30, payment to Federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed $50 per blood draw. These individuals may not receive any other payment or non-monetary compensation for participation in a research study unless they are off-duty or on-leave during the time they are participating in the protocol.

    - **Confidentiality for Military Personnel:** Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

2. **Site Visits:** The USAMRMC ORP HRPO conducts site visits as part of its responsibility for compliance oversight.

   Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues are posted at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo***.***

3. **Protocol Submission Format:** The ORP HRPO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself, should be included with protocol submissions. An HRPO protocol submission form should be completed and submitted with each protocol.

4. **Research involving the use of FDA-regulated products** (i.e., drugs, devices, in vitro diagnostics) in which the focus of the study is on the safety or effectiveness of the product requires IRB review in accordance with 21 CFR 50 and 21 CFR 56.

C. Clinical Trial Registry

PIs are required to register clinical trials individually on https://clinicaltrials.gov/ using a Secondary Protocol ID number designation of "CDMRP-eBRAP Log Number" (e.g., CDMRP-PC19####). If several protocols exist under the same application, the Secondary Protocol ID number must be designated "CDMRP-eBRAP Log Number-A, B, C, etc." (e.g., CDMRP-PC19####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (see https://prsinfo.clinicaltrials.gov/, click on "Support Materials (including data element definitions)") are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85.

D. Research Involving Recombinant DNA Molecules

The recipient assures that all work involving the use of recombinant DNA will be in compliance with guidance provided at https://osp.od.nih.gov/biotechnology/nih-guidelines/.

APPENDIX 2

REPORTING REQUIREMENTS AND ADMINISTRATIVE INFORMATION

A. Reporting Requirements for Awards

The Government requires periodic reports to be submitted to continue the research and funding through the entire period of performance. Specific reports required by the Government will be described in each award and may include:

- Technical/Scientific:
    - In addition to annual progress reports, the Terms and Conditions of the award will indicate any additional reporting required.
    - Monthly progress reports (at the discretion of the Grants Officer)
    - Final progress report
    - In-progress reviews
    - Quad Chart: The Quad Chart template is a one-page Word document or PowerPoint file that must be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm, and completed for submission with the application.
    - Award Chart: The Award Chart template is a one-slide PowerPoint file that must be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm and completed for submission with the application.

    USAMRMC research progress reporting requirements and instructions can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting.
- Fiscal (SF425 "Federal Financial Report"):
    - Quarterly or annual reports
    - Final report
- Regulatory:
    - Research Involving Human Subjects: For DoD awards that include funding to support research with human subjects, the USAMRMC's HRPO requires submission of institutional continuing review reports and study event reports. Instructions are found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.
    - Research Involving Animals: For DoD awards that include funding to support animal studies, staff from the USAMRMC's ACURO will contact the PI regarding submission requirements and deadlines. Questions related to ACURO review and

approval should be directed to the ACURO central email account at usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil.

The Government may request additional reports, which will be identified prior to the award.

B. Post-Award Organization and Principal Investigator Changes

Transfer of Award to New Organization: Unless restricted by the specific Program Announcement, a change in organizational affiliation will be considered on a case-by-case basis by the USAMRAA Grants Officer. If approved, the PI's original organization will be required to agree to relinquish the award. The new organization will be required to resubmit the entire application on behalf of the PI, including regulatory documentation. Extended times for transfer may put the award funding at risk. A transfer will not, unless under extraordinary circumstances, be allowed for any organization that includes a study site/clinical trial at its location. Organization transfers are not allowed in the last year of the performance period.

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

C. Disclosure of Proprietary Information

Do not include proprietary information in a pre-application or abstract. Proprietary information should only be included in a full application if necessary for evaluation.

Proprietary information submitted in an application may be disclosed outside the Government for the sole purpose of evaluation. Evaluators must agree that proprietary information in the application will be used for evaluation purposes only and will not be further disclosed or used. All applications may be subject to public release under the Freedom of Information Act (FOIA).

Applications for funded projects will be subject to public release under the FOIA to the extent that they are incorporated in an award document; applications that are not selected for funding will not be subject to public release.

D. Marking of Proprietary Information

Conspicuously and legibly mark any proprietary information that is included in the application.

E. Inquiry Review

If an application is not recommended for funding, the organization or PI may submit an inquiry within 15 business days after the notification email is sent. Inquiries submitted after 15 business days will not be considered.

The inquiry must specifically address a factual or procedural error that is believed to have occurred during review of the application. A perceived factual error is an error in the review (peer or programmatic) that is restricted to, or based on, a fact. Inquiries in response to funding

recommendations should be submitted to the USAMRAA Grants Officer through the CDMRP Help Desk at help@eBRAP.org. An inquiry review panel will determine whether an error occurred in either peer or programmatic review and, if so, recommend corrective action where appropriate. The determination of an error in the review process is not a guarantee of funding. Considering the recommendation of the inquiry review panel, a final determination will be made by the USAMRAA Grants Officer and is not subject to appeal. Questions related to the inquiry review process prior to or after submitting an inquiry should be directed to the CDMRP Help Desk at help@eBRAP.org.

F. Information Service

Applicants may use the technical reference facilities of the U.S. Department of Commerce National Technical Information Service (https://www.ntis.gov) to obtain information about existing research to avoid duplication of scientific and engineering effort.

G. Freedom of Information Act Requests

The FOIA (5 USC 552) provides a statutory basis for public access to official Government records. The definition of "records" includes documentation received by the Government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act (www.usdoj.gov/oip/index.html).

When a FOIA request asks for information contained in a successful application that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRMC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of USAMRMC's intent to release and will be provided a reasonable opportunity to assert available action.

H. Information Release

A recipient of an award will be required to agree to the release of information pertaining to the research and development supported by the Federal agency. "Information" includes but is not limited to news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

The following statements must be included in all information releases:

(1) All releases shall identify the award number and include a statement acknowledging the Federal sponsoring agency. The release shall also contain a statement that the opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the DoD. The requirement with specific language will be included in the award notice. Below is an example:

"This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency J9, Research and Development Directorate, through the (*insert program name*) under Award No. (W81XWH-19-1-XXXX). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense."

(2) "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture." Include required assurances, approvals, documents and information specified on the ACURO website. (https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro)

(3) "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules." (https://www.nih.gov/)

(4) "In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories." (https://www.cdc.gov/biosafety)

Failure to include the above statements and adhere to the above regulations, when required, may result in loss of funding.

I. Contracted Fundamental Research

Any awards to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DoD definition of "Contracted Fundamental Research." The results of this research are to be unrestricted to the maximum extent possible. The research shall not be considered fundamental in those rare and exceptional circumstances where the effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the award.

J. Sharing of Application Information

The USAMRMC shares application information with other Federal funding agencies (e.g., NIH, National Science Foundation, Department of Veterans Affairs) to inform funding priorities and decisions, and to increase transparency. In addition, award data are made available to the public through the CDMRP website and to other organizations such as the International Cancer Research Partnership. By sharing and leveraging this information, duplication of effort can be avoided, allowing for the support of more investigators with Federal funds. The CDMRP believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Updates on CDMRP-funded awards including awardee information and published results are shared on the Defense Technical Information Center (DTIC).

K. Sharing of Data and Research Resources

Data and research resources generated by funded research should be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public. The expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded by the Program Announcement. This includes all data and research resources generated during the project's period of performance as annotated in the assistance agreement:

- **Unique Data** are defined as data that cannot be readily replicated. Examples of unique data include large surveys that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases. (Adapted from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique.)

- **Final Research Data** are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens. (Adapted from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique.)

- **Research Resources** include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools, methods, laboratory equipment and machines. (Adapted from https://grants.nih.gov/grants/intell-property_64FR72090.pdf.)

Data and research resources generated from CDMRP-funded research should be made as widely available as possible while safeguarding the privacy of participants and protecting confidential and proprietary data and third-party intellectual property.

By sharing and leveraging data and research resources, duplication of effort can be avoided, allowing for the support of more investigators with Federal funds. The USAMRMC believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Depending on the Program Announcement, the PI may be required to participate in the following:

- Traumatic Brain Injury: If the project includes traumatic brain injury (TBI) research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System (https://fitbir.nih.gov).

- Clinical Trials: If the project includes a clinical trial(s), the PI may be required to register the clinical trial(s) individually on the registry and database ClinicalTrials.gov (https://www.clinicaltrials.gov/).

- Systems and/or Integrative Biology: PI's conducting military relevant human and/or animal biomedical research may be required to make data generated via an award, available to the research community by depositing research data in the SysBioCube system (https://sysbiocube-abcc.ncifcrf.gov/).

For additional information on CDMRP's expectations and policies for data-sharing, refer to "Policy on Sharing Data & Research Resources," available on eBRAP under Resources and Reference Material at https://ebrap.org/eBRAP/public/Program.htm. For unique data-sharing guidelines and requirements, refer to the instructions in the specific Program Announcement.

L. Property/Equipment

Unless otherwise specified in the award, the title to equipment or other tangible property acquired with Government funds will vest in institutions of higher education or with non-profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the organization for the Government. Title to equipment or other tangible property acquired by for-profit organizations will conditionally vest in the organization subject to the requirements of the DoD Grant and Agreement Regulations (DoDGARs), Part 34.21. However, if the award is subsequently transferred to a new organization, the DoD reserves the right to require the transfer of equipment acquired with the award funds to the Federal Government or to an eligible third party.

M. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (35 USC 200 et seq.), the recipient and collaborators may elect to retain title to their subject inventions, subject to meeting the reporting and patent filing requirements and retained rights to the U.S. Government. The U.S. Government shall, at a minimum, retain non-exclusive rights for the use of such inventions. Instructions in the assistance agreement concerning subject inventions must be followed.

APPENDIX 3
QUALIFICATION AND RESTRICTIONS INFORMATION

A. Recipient Qualification

To protect the public interest, the Federal Government ensures the integrity of Federal programs by conducting business with qualified recipients only. According to the standards of DoDGARs 22.415, a potential qualified recipient must (1) have the management capability and adequate financial and technical resources, given those that would be made available through the grant or cooperative agreement, to execute the program of activities envisioned under the grant or cooperative agreement; (2) have a satisfactory record of executing such programs or activities, if it is a prior recipient of an award; (3) have a satisfactory record of integrity and business ethics; and (4) be otherwise qualified and eligible to receive a grant or cooperative agreement under applicable laws and regulations (see DoDGARs 22.420(c)).

The USAMRMC utilizes the Exclusions within the Performance Information functional area of SAM to identify individuals and organizations unqualified to receive Federal awards. More information about Exclusions reported in SAM is available at https://www.sam.gov/portal. The USAMRMC also reviews and considers information about the applicant in the Office of Management and Budget (OMB)-designated integrity and performance system, currently the Federal Awardee Performance and Integrity Information System (FAPIIS), prior to making an award, as described in the Program Announcement, Section E.3.

B. J-1 Visa Waiver

Each organization, including organizations located outside of the United States, is responsible for ensuring that the personnel associated with any application recommended for funding are able to complete the work without intercession by the DoD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

Note: The Federal Government will not provide funds to support scientists from countries meeting the criteria for designation as a State Sponsor of Terrorism (https://www.state.gov/j/ct/list/c14151.htm). Additional information on J-1 Visa Waivers can be located at the following Department of State website: travel.state.gov/visa/temp..

C. Post-Employment Restrictions

There are certain post-employment restrictions on former Federal officers and employees as defined in 18 USC 207. Post-employment restrictions may exist if a former Federal officer or employee participates in the proposed project; the situation should be discussed with the USAMRMC legal staff (301-619-6598) prior to expending time and effort in preparation of an application.

APPENDIX 4
FORMATTING GUIDELINES

All pre-application and application documents must be legible and should conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ among the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** Each attachment to the full application forms must be uploaded as an individual file in the format specified in the Program Announcement. All contributors to the application must use matching compatible versions of Adobe software for all PDF documents when editing and preparing application components. The use of different software versions will result in corruption of the submitted file.

- **Font Size:** 12 point, not condensed.

- **Font Type:** Times New Roman.

- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).

- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).

- **Margins:** At least 0.5 inch (1.27 cm) in all directions.

- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).

- **Color, High-Resolution, and Multimedia Objects:** Project narratives and pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bitmap and TIFF formats are not allowed. Please note that these types of objects are not allowed in the technical and public abstracts.

- **Scanning Resolution:** 100 to 150 dots per inch.

- **Internet URLs:** Uniform Resource Locators (URLs), or web addresses, directing reviewers to websites that contain additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the application are encouraged.

- **Language:** All documents must be submitted in English, unless otherwise specified in the Program Announcement (e.g., foreign transcripts submitted with English translations).

- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.

- **Page Numbering:** Should not be used.

- **Recommended Attachment Size:** Individual attachments should be no larger than 20 MB. ***If the file size for the entire Grants.gov application package will or may exceed 200 MB, applicants should contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that the file will be accepted or for other guidance.***

APPENDIX 5
NATIONAL POLICY REQUIREMENTS

The National Policy Requirements are available in full text at https://www.usamraa.army.mil/Pages/Resources.aspx. For additional regulatory requirements regarding safety, surety, and environmental requirements, and for use of animal and human subjects in research, refer to this General Applications Instructions, Appendix 1.

A. Certification

Certification of compliance with the national policy requirement regarding lobbying activities is required from all recipients of awards over $100,000. Submission of this certification is required by 31 USC 1352 and is a prerequisite for making or entering into an award over $100,000. Complete SFLLL (Disclosure of Lobbying Activities), if applicable, and attach to Block 18 of the SF424 (Research & Related) (Application for Federal Assistance) Form.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

By signing an application, the applicant certifies, to the best of his or her knowledge and belief, that:

(1) No Federally appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, and the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid, or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit SFLLL (Disclosure of Lobbying Activities), in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 1352 USC 31. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

B. Representations

All extramural applicants are required to complete the representations below and submit with each application. The form for completion and submission is posted in eBRAP (https://ebrap.org/eBRAP/public/Program.htm). Upload the form into Grants.gov under Attachments.

Representations Regarding Unpaid Federal Tax Liabilities and Conviction of Felony Criminal Violations Under Any Federal Law

At the time of application submission, the applicant organization represents that it:

(1) Is _____ Is not _____ a Corporation ("Corporation" means any entity, including any institution of higher education, other nonprofit organization, or for-profit entity that has filed articles of incorporation). If the organization is a corporation, complete (2) and (3) below.

(2) Is_____ Is not _____ a Corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.

(3) Is____ Is not _____ a Corporation that was convicted of a criminal violation under any Federal law within the preceding 24 months.

NOTE: If the applicant organization responds in the affirmative to either (2) or (3) of the above representations, the applicant is ineligible to receive an award unless the agency suspension and debarment official has considered suspension or debarment and determined that further action is not required to protect the Government's interests. The applicant organization therefore will be required to provide information about its tax liability and/or conviction, upon request, to the Grants Officer, to facilitate completion of the required consideration before award decisions are made.

In accordance with DoD appropriations, the following representation is required. The applicant, by its signature on the SF424 Research & Related, represents:

Representation Regarding the Prohibition on Using Funds Under Grants and Cooperative Agreements with Entities That Require Certain Internal Confidentiality Agreements.

By submission of its application, the applicant represents that it does not require any of its employees, contractors, or subrecipients seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting those employees, contractors, or subrecipients from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information. Note that (1) the basis for this representation is a prohibition in Section 743 of the Financial Services and General Government Appropriations Act, 2015 (Division E of the Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113-235) and any successor provision of law on making funds available through

grants and cooperative agreements to entities with certain internal confidentiality agreements or statements; and (2) Section 743 states that it does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

National Policy Requirements

The recipient must comply with the following requirements, as applicable. The full text of National Policy Requirements is available at https://www.usamraa.army.mil/Pages/Resources.aspx. Awards will incorporate the most recent set of National Policy Requirements available at the time of award.

- Nondiscrimination
- Environmental Standards
- Live Organisms (Human Subjects and Animals)
- Debarment and Suspension
- Drug-Free Workplace
- Lobbying
- Officials Not to Benefit
- Hatch Act
- Native American Graves Protection and Repatriation Act
- Fly America Act
- Use of United States Flag Vessels
- Research Misconduct
- Requirements for an Institution of Higher Education Concerning Military Recruiters and Reserve Officer Training Corps
- Historic Preservation
- Relocation and Real Property Acquisition
- Confidentiality of Patient Records
- Pro-Children Act
- Constitution Day
- Trafficking in Persons
- Whistleblower Protections
- Certain Internal Confidentiality Agreements

APPENDIX 6
ACRONYM LIST

A&R	Alteration and Renovation
ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AOR	Authorized Organizational Representative
AVI	Audio Video Interleave
CAGE	Commercial and Government Entity
CDC	Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
COI	Conflict of Interest
CRADA	Cooperative Research and Development Agreement
DA PAM	Department of the Army Pamphlet
DHHS	Department of Health and Human Services
DoD	Department of Defense
DoDI	Department of Defense Instruction
DoDGARs	Department of Defense Grant and Agreement Regulations
DTIC	Defense Technical Information Center
DUNS	Data Universal Numbering System
E-Biz	Electronic Business
eBRAP	electronic Biomedical Research Application Portal
EIN	Employer Identification Number
F&A	Facilities and Administrative
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and 2018 Information System
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
FMR	Financial Management Regulation
FOIA	Freedom of Information Act
FWA	Federalwide Assurance
G&A	General and Administrative
GSA	General Services Administration
HIPAA	Health Information Portability and Accountability Act
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
MB	Megabyte
MIPR	Military Interdepartmental Purchase Request
MPEG	Moving Picture Experts Group
NATO	North Atlantic Treaty Organization
NCAGE	NATO Commercial and Government Entity
NIH	National Institutes of Health

OHRP	Office for Human Research Protection
OMB	Office of Management and Budget
ORCID	Open Researcher and Contributor ID
ORP	Office of Research Protections
PARC	Principal Assistant Responsible for Contracting
PD	Project Director
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
RDT&E	Research, Development, Test and Evaluation
RM	Resource Management
SAM	System for Award Management
SF	Standard Form
SFLLL	Standard Form LLL
SOW	Statement of Work
TBI	Traumatic Brain Injury
TIFF	Tagged Image File Format
TIN	Tax Identification Number
UPIRTSO	Unanticipated Problems Involving Risk to Subjects or Others
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
WAV	Waveform Audio
VA	Department of Veterans Affairs