

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Toxic Exposures Research Program

Clinical Trial Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-22-TERP-CTA

**Assistance Listing 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), November 3, 2022
- **Application Submission Deadline:** 11:59 p.m. ET, December 1, 2022
- **End of Application Verification Period:** 5:00 p.m. ET, December 6, 2022
- **Peer Review:** January 2023
- **Programmatic Review:** April 2023

This program announcement must be read in conjunction with the General Application Instructions, version 702. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”

TABLE OF CONTENTS

| | | |
|--------------------|--|-----------|
| I. | OVERVIEW OF THE FUNDING OPPORTUNITY..... | 1 |
| II. | DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY | 3 |
| II.A. | Program Description..... | 3 |
| II.A.1. | TERP Definitions and FY22 Guidance | 3 |
| II.A.2. | FY22 TERP Program Goals | 5 |
| II.A.3. | FY22 TERP Topic Areas and Focus Areas/Areas of Encouragement | 6 |
| II.A.4. | Award History | 11 |
| II.B. | Award Information | 11 |
| II.C. | Eligibility Information..... | 17 |
| II.C.1. | Eligible Applicants | 17 |
| II.C.2. | Cost Sharing..... | 18 |
| II.C.3. | Other | 18 |
| II.D. | Application and Submission Information..... | 18 |
| II.D.1. | eBRAP and Grants.gov..... | 18 |
| II.D.2. | Content and Form of the Application Submission | 19 |
| II.D.3. | Unique Entity Identifier (UEI) and System for Award Management (SAM) | 46 |
| II.D.4. | Submission Dates and Times..... | 47 |
| II.D.5. | Funding Restrictions..... | 48 |
| II.D.6. | Other Submission Requirements | 49 |
| II.E. | Application Review Information | 49 |
| II.E.1. | Criteria | 49 |
| II.E.2. | Application Review and Selection Process..... | 55 |
| II.E.3. | Integrity and Performance Information..... | 56 |
| II.E.4. | Anticipated Announcement and Federal Award Dates..... | 56 |
| II.F. | Federal Award Administration Information | 57 |
| II.F.1. | Federal Award Notices..... | 57 |
| II.F.2. | Administrative and National Policy Requirements..... | 58 |
| II.F.3. | Reporting..... | 58 |
| II.G. | Federal Awarding Agency Contacts..... | 59 |
| II.G.1. | eBRAP Help Desk..... | 59 |
| II.G.2. | Grants.gov Contact Center | 59 |
| II.H. | Other Information..... | 60 |
| II.H.1. | Program Announcement and General Application Instructions Versions..... | 60 |
| II.H.2. | Administrative Actions..... | 60 |
| II.H.3. | Application Submission Checklist..... | 63 |
| APPENDIX 1: | ACRONYM LIST | 66 |

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2022 (FY22) Toxic Exposures Research Program (TERP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). The TERP was initiated in 2022 to improve the scientific understanding of pathobiology from toxic exposures, more efficiently assess comorbidities, and speed the development of treatments, cures, and preventions. The FY22 appropriation is \$30 million (M).

In June 2022, the TERP held a stakeholders meeting to engage consumers impacted by toxic exposures, advocates, other federal funders, and academic, clinical, and military subject matter experts across various fields of toxic exposures in an open dialogue forum to identify critical issues and underfunded areas in toxic exposure research and patient care. Outcomes from this meeting were considered by the TERP Programmatic Panel in developing the FY22 program. The FY22 TERP Stakeholders Booklet and Meeting Summary, including presentation materials can be found at <https://cdmrp.health.mil/terp/>.

The vision of the TERP is to minimize and mitigate the impact of military-relevant toxic exposures and improve the quality of life of those affected.

The mission of the TERP is to support innovative and impactful research aimed at identifying and understanding the pathological mechanisms, outcomes and comorbidities associated with toxic exposures in order to facilitate the prevention, diagnosis and treatment of the invisible and visible diseases and symptoms that are associated with toxic effects impacting Service Members, Veterans and the American public.

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

II.A.1. TERP Definitions and FY22 Guidance

For the purposes of this program announcement the TERP uses the following definitions:

- **Gulf War (GW):** The 1990-1991 Persian Gulf War
- **Gulf War Illness (GWI):**
 - **Case Definitions:** In 2014 the Institute of Medicine (IOM) (now called National Academy of Medicine) released a report, “Chronic Multisymptom Illness in Gulf War Veterans: Case Definitions Reexamined” (available online at https://www.ncbi.nlm.nih.gov/books/NBK268875/pdf/Bookshelf_NBK268875.pdf). In

this report, the IOM recommended the use of both the U.S. Centers for Disease Control and Prevention’s (CDC) definition of GWI and the “Kansas” definition of GWI. Applicants are encouraged to review this report as the use of these case definitions is required when proposing clinical research/clinical trials with GW Veterans. Additional information on GWI can also be found in the 2014 report of the Research Advisory Committee on Gulf War Veterans’ Illnesses, “Gulf War Illness and the Health of Gulf War Veterans: Research Update and Recommendations, 2009-2013.” This report can be found online at <https://www.va.gov/RAC-GWVI/RACReport2014Final.pdf>.

- The former Department of Defense (DOD) CDMRP Gulf War Illness Research Program (GWIRP) assembled multiple resources that applicants may find helpful if proposing studies on GWI. These resources can be found at <https://cdmrp.health.mil/gwirp/>.
- **Common Data Elements (CDEs) for GWI Clinical Trials:** Through a collaboration between the National Institutes of Health (NIH), CDC, U.S. Department of Veterans Affairs (VA), former DOD CDMRP GWIRP, and the GWI community, CDE recommendations were developed for GWI. Applicants proposing clinical trials under the Topic Area of “Gulf War Illness and Its Treatment” are strongly encouraged to review and consider the CDEs when preparing applications. Information on the GWI CDEs can be found at <https://cdmrp.health.mil/gwirp/> and in Cohen DE, Sullivan KA, McNeil RB, et al. 2022. A common language for Gulf War Illness (GWI) research studies: GWI common data elements. *Life Sciences Journal* 290:119818. doi:10.1016/j.lfs.2021.119818.
- **New Approach Methodologies (NAMs):** “Technologies and approaches that can potentially provide the same hazard and risk assessment information without the use of animal testing.” (<https://www.nationalacademies.org/event/12-09-2021/new-approach-methods-nams-for-human-health-risk-assessment-workshop-1>)
- **Neurotoxin:** “Synthetic or naturally occurring substances that damage, destroy, or impair the functioning of the central and/or peripheral nervous system.” (<https://emedicine.medscape.com/article/1743954-overview>)
- **Toxicant:** “A poison that is made by humans or that is put into the environment by human activities.” (<https://www.cancer.gov/publications/dictionaries/cancer-terms/def/toxicant>)

FY22 TERP Guidance

For FY22, the TERP is offering three award mechanisms. The Investigator-Initiated Research Award (IIRA), Translational Research Award (TRA) and, Clinical Trial Award (CTA).

It is the responsibility of the applicant to review the program announcement requirements and select the funding opportunity that aligns with the scope of the proposed research.

Applications submitted under a mechanism that is not deemed appropriate for the type and scope of research proposed will not be recommended for funding.

For FY22, the TERP has overarching [Program Goals](#) and [Topic Areas](#) that encompass Focus Areas, some of which have Areas of Encouragement. ***To meet the intent of the award mechanism, applications must articulate how the proposed research is relevant to at least one of the FY22 TERP Program Goals and addresses at least one of the FY22 TERP Topic Areas.*** While addressing one of the FY22 TERP Focus Areas and/or Areas of Encouragement is encouraged, it is not required.

Impactful and highly relevant research will be hypothesis-driven and consider the health care needs of military Service Members, Veterans, and/or the American public with symptoms, diseases, or conditions as a result of toxic exposures and/or the need to minimize toxic exposures for military and civilian populations.

Collaboration with military or VA researchers and clinicians is encouraged.

II.A.2. FY22 TERP Program Goals

To meet the intent of the award mechanism, TERP applications *must address at least one of the Program Goals listed below.* Selection of the Program Goal is the responsibility of the applicant.

The FY22 TERP Program Goals are not listed in order of importance.

- 1. *Elucidate mechanisms of how toxic exposures result in adverse effects, including, but not limited to, toxicities, malignancies, neurologic and respiratory disorders, cardiac complications, sleep disorders, immune system dysfunction, gastrointestinal issues, etc.***
 - Understand the progression from acute toxicity to long-term illness (including but not limited to GWI, cancers, respiratory conditions, Parkinson’s disease and other neurologic disorders etc.).
 - Evaluate genetic and epigenetic mechanisms and potential long-term and/or heritable outcomes.
 - Identify biologic variables that can impact disease outcome including but not limited to sex, age, physical fitness or other modifiers.
 - Identify risk factors/genetic predictors for various diseases/conditions that may occur as a result of toxic exposure.
 - Understand the role of inflammation and autoimmunity following toxic exposure and how it relates to disease/condition outcome and patient prognosis.
 - Understand complex, multi-exposure combinations and how exposure impacts outcome.
 - Address the need for preclinical models that capture the adverse outcomes of human toxic exposures.

2. ***Diagnose the effects of toxic exposures, understand the phenotypic/genotypic and clinical outcomes associated with short-term and long-term exposures and predict disease progression.***

- Understand individual exposures and their links to individual disease outcomes.
- Identify behavioral factors (smoking, substance abuse, etc.), co-morbidities and pre-existing medical conditions that may impact exposure outcomes.
- Develop diagnostic screens/assays for short-term and persistent/chronic toxic exposures (e.g., biomarkers).
- Predict long-term effects from single, intermittent or repetitive short-term exposures.

3. ***Predict and prevent toxic exposures by identifying strategies that can anticipate, identify, monitor and prevent Service Members and the American public from adverse effects of exposures to toxic substances.***

- Identify all military service-related exposures across all environments that lead to adverse health effects.
- Advance exposure assessment methodologies, including but not limited to direct-reading and integrated measurements.

4. ***Develop therapeutics, treatments and strategies to minimize symptoms and disease progression associated with toxic exposures.***

- Evaluate existing treatments.
- Advance new treatments.

II.A.3. FY22 TERP Topic Areas and Focus Areas/Areas of Encouragement

The FY22 TERP provides congressionally-directed **Topic Areas** and program-defined **Focus Areas** for each corresponding Topic Area. Topic Areas may also include **Areas of Encouragement**.

To meet the intent of the award mechanism, CTA applications ***must address at least one of the FY22 TERP Topic Areas***. Addressing **FY22 TERP Focus Areas** is encouraged. Applications that propose “Other” research outside the listed Focus Areas/Areas of Encouragement are acceptable as long as at least one Program Goal and at least one Topic Area are being addressed.

The Topic Area in conjunction with the appropriate Focus Area or “Other” Focus Area must be selected during the pre-application submission process.

Neither Topic Areas nor Focus Areas are listed in order of importance.

TOPIC AREA: Neurotoxin Exposure

Focus Areas

- 1. Understand the relationship between toxic exposures and long-term neurologic disorders, including but not limited to Parkinson’s disease, Alzheimer’s disease or other neurologic disease phenotypes.**
 - Evaluation of complex exposures (e.g., multiple exposures over different timelines) is encouraged.
- 2. Elucidate basic mechanisms of neurotoxicity/neurodegeneration resulting from toxic exposures.**
 - Understanding molecular mechanisms of neurotoxin exposures and associated disease progression to identify novel therapeutic targets is encouraged.
 - Exposures may include but are not limited to neurotoxins and prophylactic medications such as quinoline antimalarial drugs (e.g., mefloquine) and pyridostigmine bromide.
- 3. Predict, prevent and assess neurotoxin exposures.**
 - Development of approaches to assess historical exposures are encouraged.
 - Identification of and tracking diverse exposures in military environments are encouraged.
 - Development of immediate post exposure therapeutics to prevent toxic effects are encouraged.
- 4. Develop innovative treatments for people outside of the short-term therapeutic window following neurotoxin exposure.**
- 5. Identify clinical signs and symptoms or biomarkers of chronic low-level neurotoxin exposures in order to provide effective therapeutics before permanent damage occurs.**
- 6. Understand the relationship between neurotoxin exposures and concurrent and/or comorbid neurological and psychological disorders.**
- 7. Other research focused on neurotoxin exposure that addresses a TERP Program Goal.**

TOPIC AREA: Gulf War Illness (GWI) and Its Treatment

Focus Areas

- 1. Rapidly advance effective treatments for ill Gulf War Veterans with an emphasis on those treatment regimens that can be repurposed and are readily and clinically available.**

- Treatment studies proposing clinical and confirmatory studies using objective biomarkers to demonstrate efficacy are encouraged.
 - Treatments that address symptoms and aim to improve quality of life and/or are individualized for patients are encouraged.
 - Clinical trials with a clear description of transition plan and path forward with U.S. Food and Drug Administration (FDA) compliance to advance treatments are encouraged.
- 2. Identify and validate objective biomarkers for the diagnosis and monitoring of GWI and its progression and/or for assessing treatment efficacy.**
 - 3. Evaluate the pathological and molecular mechanisms associated with GWI.**
 - Mechanistic studies having clear implications for translational studies that are relevant to humans are encouraged.
 - Translational studies that have near-term impacts on the ill GW Veteran populations are encouraged.
 - Mechanistic studies that consider the aging process and associated comorbidities are encouraged.
 - 4. Evaluate non-pharmacologic treatments (e.g., therapies/programs/services) that will significantly benefit the quality of life for the GWI patient community.**
 - 5. Other research focused on GWI and its treatment that addresses a TERP Program Goal.**

TOPIC AREA: Airborne Hazards and Burn Pits

Focus Areas

- 1. Develop noninvasive diagnostic screening, tests and assays that can differentiate among respiratory diseases/conditions.**
- 2. Improve exposure assessment methodologies to detect and understand respiratory exposures, associated risk of exposures and potential outcomes.**
- 3. Identify toxicants associated with airborne hazards and elucidate mechanisms of associated effects on human health.**
 - Studies that focus on health outcomes of airborne/burn pit exposure on any/all bodily systems, including but not limited to respiratory, gastrointestinal, immune, neurologic, and cardiac are encouraged.
- 4. Determine long-term outcomes of toxic exposures associated with burn pits and other militarily relevant airborne hazards, focusing on longitudinal studies of Service Members and Veterans.**

- Studies that address long-term health outcomes associated with burn pit and airborne hazard exposure including but not limited to cancers (associated mechanisms of carcinogenesis/tumorigenesis), chronic respiratory issues or other diseases/conditions/symptoms that may occur are encouraged.
- 5. Understand clinical phenotypes associated with burn pit and airborne hazard exposure and integrate with exposure assessment data.**
 - The use of big data and/or machine learning, including the linkage of multiple databases is encouraged.
 - 6. Other research focused on airborne hazards and burn pits that addresses a TERP Program Goal.**

TOPIC AREA: Other Military Service-Related Toxic Exposures in General, Including Prophylactic Medications, Pesticides, Organophosphates, Toxic Industrial Chemicals, Materials, Metals, and Minerals

Focus Areas

- 1. Understand the effects, impacts and outcomes of various timescale exposures (short-term, sub-chronic, and chronic) and complex exposures (repeated and mixtures) as they pertain to multiple human biologic systems and pathways.**
- 2. Elucidate mechanisms associated with direct (irritant) and systemic effects of exposure to chemicals, metals, materials and minerals.**
- 3. Investigate mechanisms associated with neurotoxicity or other adverse outcomes associated with exposure to prophylactic medications including but not limited to, quinoline antimalarial drugs (e.g., mefloquine), pyridostigmine bromide, and novel compounds.**
- 4. Evaluate long-term effects of military toxicant exposures in exposed human populations, including Veterans.**
- 5. Other research focused on other military service-related toxic exposures that addresses a TERP Program Goal.**

The list below includes areas of encouragement that are recommended but not required and may apply to all of the above “Other Military Service-Related Toxic Exposures” Focus Areas:

- Studies that address toxicodynamics and toxicokinetics are encouraged.
- Approaches to differentiate occupational vs. non-occupational exposures are encouraged.
- Development of treatment and therapeutic strategies for constellations of acute and chronic effects of toxic exposures that will have a near-term impact on Service members, Veterans and the American public are encouraged.

- Applications to this Topic Area are encouraged (but not required) to address one or more of the exposures listed below. *Any proposed exposure must be relevant to military Service Members, Veterans and/or the American public.*
 - Radiation and electromagnetic field (EMF) exposures in combination with other exposures
 - Toxic/rare earth metals
 - Other metals
 - Plastics, plasticizers, microplastics, di(2-ethylhexyl) phthalate (DEHP) in plastics
 - Toxic minerals, including asbestos
 - Lipophilic toxicants, including legacy persistent organic pollutants
 - Polycyclic aromatic hydrocarbons (PAHs)
 - Perfluoroalkyl and polyfluoroalkyl substances (PFAS) including new generation PFAS (e.g., Gen X), legacy PFAS, or a combination of new and legacy PFAS together
 - Particulate matter (PM)
 - Prophylactic medications
 - Pesticides, nerve agents, herbicides and insect repellants, including but not limited to organophosphates and carbamates
 - Endocrine disrupting chemicals
 - Fuels and other petroleum products

| Requirements for Application Submission | |
|--|---|
| <u>FY22 TERP Program Goals</u> | Must address at least one |
| <u>FY22 TERP Topic Areas</u> | Must address at least one |
| <u>FY22 TERP Focus Areas</u> | Encouraged but not required; a selection of “Other” is permitted as long as the application addresses at least one Program Goal and at least one Topic Area |
| <u>FY22 TERP Areas of Encouragement</u> | Encouraged but not required; as long as the application addresses at least one Program Goal and at least one Topic Area |

Program Goal(s) and Topic Area(s) as well as the appropriate Focus Area(s), or the “Other” Focus Area(s) should be selected during the pre-application submission process and addressed in detail in the full application submission.

II.A.4. Award History

The TERP CTA mechanism is being offered for the first time in FY22.

II.B. Award Information

The FY22 TERP CTA is intended to support the rapid implementation of clinical trials with the potential to have a significant impact on the prevention, treatment, or management of symptoms, diseases, or conditions associated with or resulting from toxic exposures. *To meet the intent of the award mechanism, applications must address at least one of the FY22 TERP Programmatic Goals and at least one of the FY22 TERP Topic Areas.*

Proposed projects may range from small proof-of-concept clinical trials (e.g., pilot, first-in-human, phase 0) designed to demonstrate feasibility or inform the design of more advanced trials, through large-scale trials to determine efficacy in relevant patient populations. Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs or biologics), devices, clinical guidance, and/or emerging approaches and technologies. It is anticipated that outcomes from studies funded by this award will follow a clinical development plan that advances the research to FDA device or drug approval and/or establishment of clinical practice guidelines, as applicable.

Applications to the TERP CTA mechanism must support a clinical trial and may not be used for animal or preclinical research studies. The application will be withdrawn if the proposed research is not a clinical trial.

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. For more information, a Human Subject Resource Document is provided at <https://cdmrp.health.mil/pubs/pdf/Human%20Subjects%20Resource%20Document.pdf>.

Principal Investigators (PIs) seeking funding for a preclinical research project should consider one of the other FY22 TERP program announcements being offered.

Partnering PI Option: In order to encourage applications that include meaningful and productive collaborations between investigators, the CTA includes an option for up to three PIs to partner in one overarching study. Each PI is expected to bring distinct contributions to the application and the application should clearly demonstrate that all PIs have equal intellectual input into the design of the project. All PIs should contribute significantly to the development of the proposed research project, including Project Narrative, Statement of Work (SOW), and other required components. The application is expected to describe how the PIs' unique expertise combined as a partnership will better address the research question, how the unique expertise that each individual brings to the application is critical for the research strategy and completion of the SOW, and why the work should be done together rather than through separate efforts.

One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as a Partnering PI(s). Applicants are discouraged from being named as a Partnering PI on multiple applications unless they are clearly addressing distinct research questions. ***Individuals named as Initiating or Partnering PIs must be at the level of Assistant Professor or above.***

If recommended for funding, each Initiating and Partnering PI(s) will be named to an individual award within the recipient organization(s). For individual submission requirements for the Initiating and Partnering PI(s), refer to [Section II.D.2, Content and Form of the Application Submission](#).

Key aspects of the FY22 TERP CTA:

- **Clinical Trial Start Date:** The proposed clinical trial is expected to begin no later than 12 months after the award date or 18 months after the award date for FDA-regulated studies.
- **Clinical Impact:** The application should explicitly state how the proposed research will have a significant impact on patient care for Service Members, Veterans, and/or the American public that have been or could potentially be impacted by the effects of toxic exposures. State both the short- and long-term impacts and how the proposed research will ultimately lead to new treatments/therapeutics/interventions, to improve the quality of life for those that have been impacted by, or are likely to encounter, toxic substances.
- **Preliminary data are required:** Inclusion of preliminary data relevant to the proposed clinical trial is required. The proposed clinical trial must be based on a sound scientific rationale that is established through logical reasoning and critical review and analysis of the relevant literature.
- **Study Population:** The application must demonstrate the availability of and access to a suitable patient population that will support a meaningful outcome for the study. The application should include a discussion of how accrual goals will be achieved, as well as the strategy for inclusion of women and minorities in the clinical trial appropriate to the objectives of the study.

- **Intervention Availability:** The application should demonstrate the documented availability of and access to the drug/compound, device, and/or other materials needed, as appropriate, for the proposed duration of the study.
- **Personnel and Environment:** The application should demonstrate the study team's expertise and experience in all aspects of conducting clinical trials, including appropriate statistical analysis, data management, knowledge of FDA processes and experience interacting with the FDA including previous FDA submissions (if applicable). The application should include a study coordinator(s) who will guide the clinical protocol through the local Institutional Review Board (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 show strong institutional support and, if applicable, a commitment to serve as the FDA regulatory sponsor, ensuring all sponsor responsibilities described in the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312), Subpart D, are fulfilled.
 - Participation of at least one military or Veteran consumer as a member of the research team to contribute to the development of the research question, project design, oversight, and evaluation, as well as other significant aspects of the proposed project is strongly encouraged.
 - For the purposes of the FY22 TERP, a consumer is a person living with a disease, injury, or condition or may be a family member or caregiver of a person living with a disease/injury/condition related to toxic exposure. The consumer must be an active participant in an advocacy, outreach, or support organization, or if military personnel on active duty, be approved to participate by their commanding officer.
- **Statistical Analysis and Data Management Plans:** The application should include a clearly articulated statistical analysis plan, a power analysis reflecting sample size projections that will answer the objectives of the study and a 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.
- If the proposed clinical trial involves the use of a drug that has not been approved by the FDA or international equivalent for the proposed investigational use, then an Investigational New Drug (IND) application to the FDA that meets all requirements under 21 CFR 312 may be required. It is the responsibility of the applicant to provide evidence from the IRB of record or the FDA if an IND is not required. If an IND is required, the IND application ***must be submitted to the FDA within 6 months of the award date.*** The IND 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 IND application) and indication to be tested in the proposed clinical trial. For more information on IND applications, the FDA has provided guidance at: <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm>.

- If the investigational product is a device, then an Investigational Device Exemption (IDE) application to the FDA that meets all requirements under 21 CFR 812 may be required. It is the responsibility of the applicant to provide evidence if an IDE is not required or the device qualifies for an abbreviated IDE. If an IDE is required, the IDE application ***must be submitted to the FDA within 6 months of the award date.*** The IDE should be specific for the device (i.e., should not represent a derivative or modified version of the device described in the IDE application) and indication to be tested in the proposed clinical trial.

Proposed research may be related to diseases, conditions, or symptoms supported by other CDMRP programs; however, TERP applications must be relevant to toxic exposures and be responsive to the [FY22 TERP Program Goals](#) and [Topic Areas](#).

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the study in the NIH clinical trials registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 1, Section B, for further details.

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 USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of ***all required and complete*** documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview 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.

If the proposed research involves more than one institution, plans for the multi-institutional structure governing the research protocol(s) should be outlined. In addition, a written plan for single IRB review arrangements must be provided for research conducted in the United States involving more than one institution. The lead institution 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. Communication and data transfer between or 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 on by all participating institutions is also required for multi-institutional clinical trials.

Use of DOD or VA Resources: If the proposed research involves access to active-duty military or Veteran patient populations and/or DOD or VA 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. Refer to [Section II.D.2.b.ii, Full Application Submission](#)

[Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

Access to Data and/or Previously Collected Biospecimens

The table below is provided as a reference and is not an exhaustive list of all resources that may be applicable to the proposed research. Researchers are not required to use any of the following limited examples or any one particular dataset.

The TERP does not provide access to any of the below resources and/or control the information presented on the websites listed below.

| Resource | Website |
|---|---|
| Boston Biorepository, Recruitment and Integrated Network for GWI (BBRAIN) | https://sites.bu.edu/bbrain/ |
| Defense Health Affairs (DHA) Data Sharing Agreement Information | https://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Data-Sharing-Agreements |
| Defense Manpower Data Center (DMDC) | https://dwp.dmdc.osd.mil/dwp/app/main |
| Defense Medical Surveillance System (DMSS) | https://www.health.mil/Military-Health-Topics/Health-Readiness/AFHSD/Epidemiology-and-Analysis |
| Defense Occupational and Environmental Health Readiness System (DOEHRS) | https://phc.amedd.army.mil/topics/envirohealth/hrasm/Pages/DOE_HRS_Resources.aspx |
| DoD Serum Repository (DoDSR) | https://www.health.mil/Military-Health-Topics/Health-Readiness/AFHSD/Epidemiology-and-Analysis |
| Gulf War Illness Clinical Trials & Interventions Consortium (GWICTIC) | https://www.nova.edu/nim/GWICTIC/index.html |
| Individual Longitudinal Exposure Record (ILER) | https://iler.csd.disa.mil/iler/app/hipaa?execution=e2s1 |
| Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC) | https://maveric.org/ |
| Millennium Cohort Study | https://millenniumcohort.org/ |

| Resource | Website |
|--|---|
| The Million Veteran Program (MVP) | https://www.research.va.gov/MVP/default.cfm |
| VA Environmental Health Registries | https://www.publichealth.va.gov/exposures/benefits/registry-evaluation.asp |
| VA Gulf War Veterans' Illnesses Biorepository Brain Bank (GWVIB) | https://www.research.va.gov/programs/tissue_banking/gwvib/default.cfm |
| VA Gulf War Era Cohort and Biorepository (GWECB) | https://www.research.va.gov/programs/csp/585/default.cfm |

The types of awards made under the program announcement will be **assistance agreements**. An assistance 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. 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. 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, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY22 TERP CTA will not exceed **\$1,500,000** for the Single PI Option and **\$2,500,000** for the Partnering PI Option. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2023. For additional information, refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately \$8.8M to fund approximately three CTA 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 FY22 funding opportunity will be funded with FY22 funds, which will expire for use on September 30, 2028.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and 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, federal government organizations 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. ***Intramural Submission: An application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

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

II.C.1.b. Principal Investigator

Extramural and intramural (DOD) investigators at or above the level of Assistant Professor (or equivalent) may be named by the organization as the PI or Partnering PI(s) on the application.

An intramural investigator is defined as a DOD military or civilian employee working within a DOD laboratory or military treatment facility, or working in a DOD activity embedded within a civilian medical center. Submissions from intramural (DOD) organizations are encouraged for this program announcement. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborators involvement.

Applicants are discouraged from being named as a Partnering PI on multiple applications unless they are clearly addressing distinct research questions.

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Submission of applications proposing classified research will be administratively withdrawn.

II.D.1. eBRAP and Grants.gov

eBRAP (<https://ebrap.org>) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (<https://grants.gov>), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

Grants.gov is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

Extramural Submission:

- 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 Submission:

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

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

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

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1, Full Application Guidelines](#)).

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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

Partnering PI Option: The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. ***Each Partnering PI must follow the link in the notification email in order to associate their full application package with that of the Initiating PI. After following the link, each Partnering PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP.*** If not previously registered, the Partnering PI(s) must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI(s). Applicants are urged to complete these steps as soon as possible. If they are not completed, the Partnering PI(s) will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full application package components to eBRAP.

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

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

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

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

All pre-application components must be submitted by the Initiating PI through eBRAP (<https://eBRAP.org>).

The applicant organization and associated PI(s) 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 applicant must contact the eBRAP 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.

When starting the pre-application, PIs should ensure that they select the appropriate mechanism option in eBRAP:

- Clinical Trial Award – Single PI Option (CTA)
- Clinical Trial Award – Partnering PI Option (CTA-PPIO)

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>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

[Requirements for Application Submission](#)

- **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 applicants 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.

[FY22 TERP 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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

For the Partnering PI Option, the Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the [FY22 TERP Program Goal\(s\)](#) and [FY22 TERP Topic Area\(s\)](#) under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during peer or programmatic review. *Full application submission does not require an invitation, and may take place after a completed LOI pre-application submission is accepted.*

- **Tab 6 – Submit Pre-Application**

This tab must be completed for the pre-application to be accepted and processed.

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

Applications will not be accepted unless a complete pre-application package (LOI) has been received and processed.

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://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.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

| Extramural Submissions | Intramural DOD Submissions |
|--|---|
| Application Package Location | |
| Download application package components for W81XWH-22-TERP-CTA from Grants.gov (https://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-22-TERP-CTA 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. | <p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p> |

| Extramural Submissions | Intramural DOD Submissions |
|---|---|
| <p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • 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 | <p>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:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>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.</p> |
| Application Package Submission | |
| <p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>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.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. Do not password protect any files of the application package, including the Project Narrative.</p> | <p>Submit package components to eBRAP (https://ebrap.org).</p> <p>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. Do not password protect any files of the application package, including the Project Narrative.</p> |

| Extramural Submissions | Intramural DOD Submissions |
|---|---|
| <u>Application Verification Period</u> | |
| <p>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 <i>with the exception of the Project Narrative and Research & Related Budget Form</i>.</p> | <p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form</i>. 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.</p> |
| Further Information | |
| <p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p> | <p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p> |

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

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

Attachments:

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

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (20-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 (uniform resource locators) 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.

The Project Narrative is NOT the formal clinical trial protocol. Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 5-8 described below. Failure to submit these attachments as part of the application package will result in rejection of the entire application.

Describe the proposed project in detail using the outline below. *Funding from this award mechanism must support a clinical trial and cannot be used for animal or preclinical research studies.*

Background:

- **Background/Rationale:** Describe in detail the scientific rationale for the study. Applications must include preliminary (published or unpublished clinical or preclinical) data relevant to the proposed clinical trial. The proposed clinical trial must be based on a sound scientific rationale that is established through logical reasoning and critical review and analysis of the relevant literature. Provide a summary of other relevant ongoing, planned, or completed clinical trials and describe how the proposed study differs from other relevant or recently completed research. Describe how the proposed intervention, if applicable, compares/improves on standard of care or other available interventions. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable). The background section should clearly support the choice of the study variable and should explain the basis for the study questions and/or hypotheses. State the relevance of the proposed research and

applicability of the anticipated findings to the intent of the mechanism (refer to [Section II.B, Award Information](#)) and to ***at least one of the [FY22 TERP Program Goals](#) and at least one of the [FY22 TERP Topic Areas](#)***. Though not required, if addressing one of the FY22 TERP Focus Areas, provide an indication of how the proposed studies are relevant to the TERP Focus Areas and/or Areas of Encouragement.

- If applicable, describe any military or Veteran consumer engagement that was performed and how it helped formulate the hypothesis/objective and research strategy. If consumers will be engaged throughout the study, please clearly indicate their role/anticipated contributions during the period of the performance. If applicable, full details of the Consumer Engagement Statement should be provided in [Attachment 9](#).

If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.

- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses. This information should agree with the primary aims and associated tasks described in the SOW ([Attachment 4](#)).
- **Study Design:** Describe the type of study to be performed (e.g., treatment, prevention, diagnostic), the study phase or class (if applicable), and the study model (e.g., single group, parallel, crossover). Outline the proposed methodology in sufficient detail to show a clear course of action. Discuss the feasibility of the proposed project and how it will be completed within the proposed period of performance.
 - Identify the intervention to be tested and describe the projected results. *Additional details should be provided in [Attachment 5, Intervention](#).*
 - 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 and justify the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical trial.
 - 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). *Additional details should be provided in [Attachment 6, Human Subject Recruitment and Safety Procedures](#).*

- 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.
- **Statistical Plan and Data Analysis:** 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 and all proposed correlative studies. 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. For phase 3 clinical trials, describe plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the 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 demonstrates 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.
- **Letters of Commitment (if applicable):** 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 the availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.
- **Intellectual Property:** Information can be found in 2 CFR 200.315, “Intangible Property.”
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community, including the sharing of de-identified data and samples with data and biospecimen repositories. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation 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.
- **Quad Chart:** Provide a Quad Chart for the proposed project. The format for the Quad Chart is available on the eBRAP “Funding Opportunities & Forms” web page at (<https://ebrap.org/eBRAP/public/Program.htm>).
- **Attachment 3: Technical and Lay Abstracts (two-page limit): Upload as “Abstracts.pdf”.** 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 (one-page limit): Technical abstracts should be written using the outline below. The technical abstract should provide an appropriate description of the project’s key aspects; clarity and completeness within the space limits of the technical abstract are highly important.

Describe the proposed research project, including the following elements:

- **Background/Rationale:** Present the scientific rationale and reasoning behind the proposed research project.
- **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:** Explicitly state how the proposed research will have a significant impact on patient care for Service Members, Veterans, and/or the American public that have been or could potentially be impacted by the effects of toxic exposures. State both the short- and long-term impacts and how the proposed research will ultimately lead to new treatments/therapeutics/interventions to improve patient care and the quality of life for those that have been impacted by, or are likely to encounter, toxic substances.

- **Relevance to the TERP:** Applications should articulate how the proposed research is relevant to at least one of the [FY22 TERP Program Goals](#) and addresses at least one of the [FY22 TERP Topic Areas](#). While not required, if applicable, also address how the application is relevant to one of the FY22 TERP Focus Areas aligned to the Topic Area(s).
- **Relevance to Military Health:** State how the proposed research is responsive to the health care needs of military Service Members and/or Veterans with GWI, exposures to neurotoxins, airborne hazards and burn pits, and other military Service-related toxic exposures as well as the general public.
- **Lay Abstract (one-page limit):** Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community.
 - Clearly describe the objectives and rationale for the proposed study and intervention in a manner *readily understood by readers without a background in science or medicine*.
 - If applicable, describe the approach implemented for engagement of military and Veteran consumers in the study.
 - Describe the ultimate applicability of the research and how it addresses at least one of the [FY22 TERP Program Goals](#) and at least one of the [FY22 TERP Topic Areas](#). While not required, if applicable, also address how the application is relevant to one of the FY22 TERP Focus Areas aligned to the Topic Area(s).
 - What types of patients will it help, and how will it help them?
 - What are the potential clinical applications and benefits?
 - How is the proposed intervention expected to improve on patient outcomes (longevity, quality of life, etc.) relative to existing treatments and/or standards of care?
 - What is the projected timeline it may take to achieve an impact on the standard of care for toxic exposures?
- **Attachment 4: Statement of Work (seven 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>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the FY22 TERP CTA, refer to the “*Suggested SOW Strategy Clinical Research*” document for guidance on preparing the SOW and use the blank SOW format titled “*Suggested SOW Format*” The SOW must be in PDF format prior to attaching.

The SOW should state the specific aims described in the Project Narrative and include a list of major tasks and subtasks that support the completion of the stated aims, including milestones for completing the aims during the period of performance. The SOW should describe only the work for which funding is being requested by this application and as applicable:

- Include the name(s) of the key personnel for each study site/sub-award site.
- Indicate the number (and type, if applicable) of research subjects and/or human anatomical samples projected or required for each task and at each site.
- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IRB and federal OHRO approvals, IND and IDE applications). Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- Indicate quarterly enrollment targets.
- If applicable, indicate timelines and approvals required to obtain access to databases, repositories or other resources.

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

- **Attachment 5: Intervention (no page limit): 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 and/or clinical needs as it relates to at least one [FY22 TERP Program Goals](#) and at least one [FY22 TERP Topic Areas](#). Describe how the intervention addresses the clinical needs and how it compares with currently available interventions and/or standards of care. 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. Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).

- **Study Procedures:** Describe the interaction with the human subject, including the study intervention that they 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) guidelines, Good Manufacturing Practices (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) Good Clinical Practices (GCP) compliance by an independent clinical trial monitor (or clinical research associate). The 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 6: Human Subject Recruitment and Safety Procedures (no page limit): Upload as “HumSubProc.pdf”. *Proposed studies should not rely on samples, reagents, or tools that are contingent upon completion of other ongoing efforts outside the scope of this research project.*** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
 - **Study Population:** Describe the study population (to whom the study findings will be generalized) (i.e., Service Members/Veterans/civilians) and the nature, approximate number, age ranges, sex/gender, race, ethnicity, and other pertinent demographic characteristics, criteria for inclusion/exclusion and methods that will be used for recruitment/accrual/retention of human subjects.
 - Describe the rationale for the selection of the subjects. 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 studies involving GW Veterans, the use of both the [CDC and Kansas case definitions](#) are required. Describe and justify any additional case definition of GWI, including any targeted illness subgroups that will be defined for the study.
 - **Enrollment Table:** For each study site, provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity.
 - **Inclusion of Women and Minorities in the 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 USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the

benefits of human subjects research. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.html>.

- Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts of the PI and/or key collaborators that will be made to achieve accrual and retention goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical research, if applicable. Provide a description of the PI and/or key collaborator's experience in recruiting human subjects/acquiring human samples/accessing databases for similar research projects. Identify any potential barriers to accrual/retention and provide mitigation plans for addressing unanticipated delays (e.g., slow accrual, attrition). Identify ongoing clinical research/trials that may compete for the same patient population and how they may impact enrollment progress.
 - If active-duty military or Veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population(s). If a non-military population will be used for the proposed research project to simulate a military exposure, explain how the population simulates the targeted population. *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.
- **Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care 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.
- **Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects and provide a draft, in English, of the Informed Consent Form. It is recommended that informed consent allows for the use of samples for future studies.
 - 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 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 application 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 exposed to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. Consider how the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study. 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:**

- ❖ Appropriate to the study’s level of risk, describe how safety monitoring 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, including 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.

- **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 7: Data Management (no page limit): Upload as “Data_Manage.pdf”.** The Data Management attachment should include the components listed below.

- **Data Management:** Describe all methods used for data collection, including 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.
- **CDEs for GWI Clinical Trials:** If proposing clinical trials with GW Veterans, the use of CDEs is strongly encouraged. If applicable, describe how the use of GWI CDEs was considered when developing the plans for the collection of clinical data and annotation of clinical samples.
- **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, including 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, including 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, including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
 - **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and 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 8: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “Regulatory.pdf”.** Answer the following questions and provide supporting documentation as applicable.
- State the product/intervention name.

For products/interventions that do not require regulation by the FDA:

- For investigator-sponsored regulatory exemptions (e.g., IND, IDE) provide evidence of institutional support. Provide evidence that the clinical trial does not require regulation by the FDA (or international equivalent).

For products that require regulation by the FDA:

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States (or international equivalent).
- If the product is marketed in the United States, 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.

- For the FY22 TERP CTA, *if an IND or IDE is required, the application must be submitted to the FDA within 6 months of award.* The IND or IDE 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. Provide the date of submission, the application number, and a copy of the FDA letter acknowledging the submission. 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., 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 a summary of any previous meetings with the FDA on development of this product. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.
- 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.
- Provide the current status for manufacturing development (e.g., manufacturer’s name, GMP-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).
- Describe the overall regulatory strategy and product development plan that will support the planned product indication/label. 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.
- **Attachment 9: Consumer Engagement Statement, (if applicable, one-page limit): Upload as “Consumer_Statement.pdf”.** If the proposed project will include consumer engagement/involvement, provide a Consumer Engagement Statement that includes the following:
 - Description of the consumer engagement approaches that will be used in the proposed study and at what points it will contribute to the research project.
 - Description of the consumer involvement and input that will be captured during the course of the proposed study and how this input will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and

- dissemination of the proposed research. Include a description of how consumer effectiveness will be assessed.
- **Attachment 10: Study Personnel and Organization (no page limit): 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, or international equivalent 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.
 - **Study Personnel Description:** Briefly describe the composition of the study team, including roles of the individuals listed in the organizational chart on the project. Study coordinator(s) and statisticians should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed research. Describe relevant background and qualifications (e.g., statistical expertise, expertise in the disease, and clinical studies) that demonstrate appropriate expertise to accomplish the proposed work, including previous interactions with the FDA, or international equivalent (if applicable). If applicable, describe how the study team composition is able to provide military-relevant subject matter expertise to the proposed research.
 - **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial involves more than one institution, 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 institution. If the research involves more than one institution, a single IRB is required for all institutions located in the United States. If applicable, describe how the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management [specimens, imaging products, etc.]) obtained during the study will be handled and shared to meet the needs of the proposed clinical trial.
 - **Partnership Statement:** *The Partnership Statement is only applicable and required within Attachment 10 for applications submitted under the Partnering PI Option.* Describe the partnership and combined expertise of the Initiating and Partnering PIs that are critical for the research strategy and completion of the SOW. Explain how the partnership will better address the research question and why the

work should be done together rather than through separate individual efforts. Explain how both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project.

The inclusion of at least one clinician on the study team is strongly encouraged.

- **Attachment 11: Questionnaires and Other Research Data Collection Instruments, if applicable (no page limit): Upload as “Data_Collection.pdf”.** The Questionnaires and Other Research Data Collection Instruments attachment should include a copy of the most recent version of 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 12: Transition Plan (three-page limit): Upload as “Transition.pdf”.** Describe the methods and strategies proposed to advance the anticipated study outcomes/products (intellectual knowledge and/or tangible materiel) to the next phase of development (clinical trials, commercialization and/or delivery to the civilian or military market) after successful completion of the proposed effort. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan.

The transition plan should include the components listed below, as appropriate and applicable to the research proposed.

- A description of the outcomes expected upon completion of the proposed research efforts. Outcomes should be relevant, measurable, and include the intended end-user.
- Details of the funding strategy that will be used to advance the outcomes to the next phase of development, commercialization (e.g., partners, funding opportunities to be applied for), and/or incorporation into patient care.
- A description of collaborations and other resources that will be used to provide continuity of development.
- Provide a brief schedule and milestones for bringing the outcomes/products to the next phase of development (e.g., further research, clinical trials, commercialization/transition to industry, delivery to the military or civilian market, incorporation into clinical practice, clearance/approval by the FDA, or international equivalent).
- For knowledge products, include the development or modification of clinical practice guidelines/recommendations, provider training materials, patient brochures, clinical support tools, scientific journal publications, models, simulations, and other 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.)
- Clearly articulate ownership rights and/or access to the appropriate 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.
 - If applicable, provide a risk analysis for cost, schedule, manufacturability, and sustainability.
 - Provide a description of how outcomes/products will be disseminated to both the scientific and consumer/stakeholder communities.
- **Attachment 13: Impact and Relevance to Military Health Statement (three-page limit): Upload as “Impact.pdf”.** The Impact and Relevance to Military Health Statement must demonstrate how the proposed project will advance at least one of the [FY22 TERP Program Goals](#) and at least one of the [FY22 TERP Topic Areas](#). While not required, if applicable, also address how the application is relevant to one of the FY22 TERP Focus Areas aligned to the Topic Area(s). The Impact and Relevance to Military Health Statement should be written in a manner that will be readily understood by readers without a background in science or medicine.
- Describe how the proposed research will reduce the burden (effects/outcomes, new exposures, etc.) of toxic exposures for military Service Members, Veterans, and/or the American public.
 - Identify the sample population(s) that will participate in the proposed intervention, describe how they represent the target population that would benefit from the intervention, and describe the potential impact and anticipated outcomes of the proposed clinical trial on the lives and health of the target population.
 - ***Describe the short-term impact:*** Detail the anticipated outcomes/products (intellectual knowledge and/or tangible materiel) that will be directly attributed to the results of the proposed clinical trial and describe anticipated short-term benefits for individuals.
 - ***Describe the long-term impact:*** Explain the anticipated long-term impact of implementing the intervention in the clinic or field, and describe the anticipated long-term benefits on patient care and/or quality of life for the targeted population(s).
 - Describe any relevant controversies or treatment issues that will be addressed by the proposed clinical trial.
 - Describe how the intervention represents an improvement over currently available interventions and/or standards of care.

- Describe how the proposed effort is responsive to the health care needs and quality of life of Service Members, Veterans, and/or other military beneficiaries.
 - If applicable, clearly articulate how the proposed research will be able to enhance readiness and recovery on the battlefield, during training, or in resource-limited environments.
 - If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest and/or patient care for toxic exposures.
 - 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.
 - Describe potential issues that might limit the impact of the proposed research and strategies that may be employed to overcome those issues.
- **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: Suggested Collaborating DOD Military Facility Budget Format, 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 a separate budget using “Suggested Collaborating DOD Military Facility Budget Format,” 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 1681[a] 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 (six-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”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- Key Personnel Biographical Sketches (six-page limit each): Upload as “Biosketch_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

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

Budget Justification (no page limit): Upload as “BudgetJustification.pdf”. The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization(s) will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.

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

- **Extramural Applications Only**

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

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

Suggested DOD Military Budget Format: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. *Note:* Applicants should complete a separate military budget using “Suggested Collaborating DOD Military Facility Budget Format” (available for download on the eBRAP “Funding Opportunities & Forms” web page [<https://ebrap.org/eBRAP/public/Program.htm>]) ([Attachment 15](#)) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

| |
|--|
| Application Components for each Partnering PI, if applying under the Partnering PI Option |
|--|

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

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

The application submission process for each Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

Attachments:

- **Attachment 4: Statement of Work (seven-page limit): Upload as “SOW.pdf”.** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and each Partnering PI should be noted for each task.
- **Attachment 14: Representations (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 15: Suggested Collaborating DOD Military Facility Budget Format: Upload as “MFBudget.pdf”.** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

Research & Related Personal Data: For extramural submissions (via Grants.gov) refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- **PI Biographical Sketch (six-page limit):** Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.
- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- **Key Personnel Biographical Sketches (six-page limit each):** Upload as “Biosketch_LastName.pdf”.

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

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

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

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for each Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.

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

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form:

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.)
- **Intramural DOD Collaborator(s):** Complete a separate military budget using the “Suggested Collaborating DOD Military Facility Budget Format” (available for download on the eBRAP “Funding Opportunities & Forms” web page [<https://ebrap.org/eBRAP/public/Program.htm>]) and upload to Grants.gov attachment form as [Attachment 15](#). (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/SAM/>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. As published in the Federal Register July 10, 2019 (<https://www.federalregister.gov/documents/2019/07/10/2019-14665/unique-entity-id-standard-for-awards-management>), the UEI for awards management generated through SAM will be used

instead of the Data Universal Numbering System (DUNS) number as of April 2022. ***All federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI.*** USAMRDC will transition to use of the UEI beginning with FY22 announcements and utilize the latest SF424, which includes the UEI. The DUNS will no longer be accepted. Applicant organizations will not go to a third-party website to obtain an identifier. During the transition, your SAM registration will automatically be assigned a new UEI displayed in SAM. (For more information, visit the General Services Administration: <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-information-kit/unique-entity-identifier-update>.) Current SAM.gov registrants are assigned their UEI and can view it within SAM.gov. ***Authorized Organizational Representatives with existing eBRAP accounts should update their organizational profile to include the UEI prior to submission of the full application to Grants.gov (see Section II.D.4, Submission Dates and Times below).*** 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

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. 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 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. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. 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 Research & Related Budget Form cannot be changed after the application submission deadline.*** 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.

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

Single PI Option:

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

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$1,500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **\$1,500,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Partnering PI Option:

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

The anticipated combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and each Partnering PI will not exceed **\$2,500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined Initiating and Partnering PI organizations' budgeted direct costs approved by the government will not exceed **\$2,500,000** or use an indirect cost rate exceeding each organization's negotiated rate.

A separate award will be made to each PI's organization.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

For this award mechanism, direct costs may be requested for travel including:

- Travel in support of multidisciplinary collaborations.

- Costs for the PI(s) to travel to one scientific/technical meeting per year. The intent of travel costs to a scientific/technical meeting is to present project information and/or disseminate project results from the FY22 TERP CTA.
- Costs for the PI(s) to present project information or disseminate project results at one DOD-sponsored meeting (e.g., Military Health System Research Symposium) during the lifetime of the award. For budget purposes, it is suggested that these costs be included in year 2 of the award in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

Must not be requested for:

- Preclinical or animal research

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.*

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following **scored criteria**, which are of equal importance:

- **Clinical Impact and Relevance to Military Health**
 - How well the sample population represents the target population that would benefit from the intervention and how impactful the anticipated outcomes of the proposed clinical trial would be on the lives and health of the target population.
 - How impactful the anticipated outcomes of the proposed clinical trial would be on patient care for Service Members, Veterans, and/or the American public that have been or could potentially be impacted by the effects of toxic exposures.

- How the anticipated short- and long-term impacts of the proposed clinical trial will ultimately lead to new treatments/therapeutics/interventions to improve the quality of life for those that have been impacted by, or are likely to encounter, toxic substances.
 - How well the short-term impact including the anticipated outcomes/products (intellectual and/or tangible materiel) that will be directly attributed to the results of the proposed clinical trial and the short-term benefits for individuals are described.
 - How well the anticipated long-term impact of implementing the intervention in the clinic or the field and long-term benefits on patient care and/or quality of life for the targeted populations are described.
 - Whether the impact statement describes how it will enhance readiness and recovery on the battlefield, during training, or in resource limited environments (if applicable), and how the proposed project aligns with DOD and/or VA areas of research interest and/or patient care for toxic exposures.
 - Whether the application provides a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit civilian population and address military need (as appropriate) and whether it describes potential issues that might limit the impact of the proposed research and strategies that may be employed to overcome these issues.
 - To what extent the proposed project will advance at least one of the [FY22 TERP Program Goals](#) and at least one of the [FY22 TERP Topic Areas](#).
- **Research Strategy and Feasibility**
 - How well the scientific background/rationale describes the relevance of the proposed research to the intent of the mechanism and at least one of the [FY22 TERP Program Goals](#) and at least one of the [FY22 TERP Topic Areas](#).
 - How well the application describes the scientific rationale for the clinical trial including preliminary (published or unpublished clinical or preclinical) data relevant to the proposed clinical trial and whether the clinical trial is based on a sound scientific rationale.
 - Whether the hypothesis or objectives of the study are clearly stated and how well the detailed specific aims, are described and aligned with the tasks in the SOW.
 - Whether the proposed project is feasible and will be completed within the proposed period of performance.
 - How well the application addresses measures to reduce bias.
 - How well the application discusses potential problem areas, alternative methods/ approaches and mitigation strategies to address potential subject loss to follow up.

- How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable.
- To what degree the data collection instruments, if applicable, are appropriate to the proposed study.
- **Intervention**
 - Whether there is evidence of who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for the proposed clinical trial.
 - To what degree the intervention addresses the clinical need(s) described.
 - How the intervention compares with currently available interventions and/or standards of care.
 - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
 - How well research procedures are clearly delineated from routine clinical procedures.
 - Whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
 - How well the application describes interactions with human subjects including the study intervention that they will experience.
 - Whether the monitoring plan describes 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.
- **Regulatory Strategy and Transition Plan**
 - How 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 includes documentation that the study is exempt from FDA regulation (or international equivalent), or that the IND or IDE application can feasibly be submitted within 6 months of award, as appropriate.
 - For investigator-sponsored regulatory exemptions (e.g., IND, IDE), whether there is evidence of appropriate institutional support.
 - Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.
 - Whether the identified next phase of development and/or commercialization is realistic.

- Whether the funding strategy described to bring the intervention to the next phase 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 are achievable to provide continuity of development.
 - 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 clinical practice, and/or approval by the FDA, or international equivalent) 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.
 - How well the application describes the manner by which outcomes/products will be disseminated to both the scientific and consumer/stakeholder communities.
- **Recruitment, Accrual, and Access to Appropriate Subject Populations**
 - How well the application addresses the availability of human subjects for the clinical trial and the prospect of their participation.
 - Whether there is sufficient evidence provided to support availability of and access to human samples/study populations required for the study and documentation of experience of the PI and/or key collaborators in recruiting human subjects/acquiring human samples/accessing databases for similar projects.
 - How well the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random) are described.
 - 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 inclusion/exclusion criteria and group assignment process meet the needs of the proposed clinical trial.
 - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate mitigation 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.
 - Whether the strategy for the inclusion of women and minorities is appropriate to the objectives of the study.
 - Whether the distribution of the proposed enrollment on the basis of sex/gender, race, and/or ethnicity is appropriate for the proposed research.
 - If applicable, whether studies using GW Veterans, include the use of both the [CDC and Kansas case definitions](#) and whether any additional case definitions of GWI are justified and well-defined for the study.
- **Statistical Plan and Data Analysis**
 - To what degree the statistical model and data analysis plan are suitable for the study objectives.
 - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
 - 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.
 - Whether the plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity for phase 3 clinical trials are appropriate for the proposed research.
 - If applicable, to what extent the use of GWI CDEs was considered when developing the plans for the collection of clinical data and annotation of clinical samples.
- **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 the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
 - 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.

- **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 clinical studies).
 - How the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
 - If applicable, how well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management [specimens, imaging products, etc.]) obtained during the study will be handled and shared to meet the needs of the proposed clinical trial. For clinical trials that involve more than one institution, to what degree the multi-institutional structure governing the research protocol(s) across all participating institutions and regulatory submission plan are described and appropriate.
 - If applicable, to what extent the study team composition is able to provide military-relevant subject matter expertise to the proposed research.
- **Partnership (only applicable to Partnering PI Option applications)**
 - Whether the partnership and combined expertise of the Initiating and Partnering PIs are critical to the research strategy and completion of the SOW.
 - To what degree the partnership will better address the research question together rather than through separate individual efforts.
 - How well the application reflects that all PIs contributed equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project.
- **Consumer Engagement (if applicable)**
 - How well the application discusses the consumer engagement approaches that will be used in the proposed study and the points during which consumers will contribute to the research project.
 - Whether the consumer involvement is well described and provides an indication of how the input/involvement will be captured, meaningfully integrated into the needs assessment, planning, design, execution, analysis, and dissemination of the proposed research and whether the application provides a clear indication of how the consumer effectiveness will be assessed.

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

- **Data and Research Resources Sharing Plan**
 - To what extent the data and resources generated during the performance of the project will be shared with the research community, including the sharing of de-identified data with data repositories.
- **Environment**
 - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
 - Whether there is evidence for appropriate institutional commitment from each participating institution.
- **Budget**
 - Whether the **direct** costs exceed the allowable direct 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 Defense Health Program and FY22 TERP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative clinical impact and relevance to military health

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, USAMRDC. *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.health.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the TERP will be provided to the PI(s) 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 200.1, 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 FY22 funds are anticipated to be made no later than September 30, 2023. 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 the USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs: An institution of higher education, hospital, or 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. Refer to the General Application Instructions, Section III.A.5.

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.

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 Grants Officer.

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

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.

New Requirement: Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, Partnering PIs (if applicable), and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

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.***

Quarterly, annual and final progress reports will be required.

The Award Terms and Conditions will specify if more frequent reporting is required.

Quarterly, annual, and final quad charts will be required within the progress reports.

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 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.

PHS Inclusion Enrollment Reporting Requirement: Enrollment reporting on the basis of sex/gender, race, and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

Awards resulting from this program announcement may entail 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 \$10M 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. These 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. eBRAP 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 eBRAP 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). The eBRAP 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 702T3b. The program announcement numeric version code will match the General Application Instructions version code 702.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application (LOI) was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Intervention ([Attachment 5](#)) is missing.
- Human Subject Recruitment and Safety Procedures ([Attachment 6](#)) is missing.
- Data Management ([Attachment 7](#)) is missing.
- Regulatory Strategy ([Attachment 8](#)) is missing.
- Transition Plan ([Attachment 12](#)) is missing.

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 applications:

- An FY22 TERP 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 FY22 TERP Programmatic Panel members can be found at <https://cdmrp.health.mil/terp/panels/panels22>.*
- 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 FY22, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.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.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The proposed research is not a clinical trial.
- The proposed research includes animal or preclinical research studies.
- The application fails to address at least one of the [FY22 TERP Program Goals](#) and at least one of the [FY22 TERP Topic Areas](#).
- The PI does not meet the eligibility criteria.

- Failure to submit all associated (Initiating and Partnering PI(s)) applications by the deadline.
- Classified research is proposed.

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 | Single or Initiating PI Completed | Partnering PI Completed |
|--|---|-----------------------------------|-------------------------|
| SF424 Research & Related Application for Federal Assistance (extramural submissions only) | Complete form as instructed. | | |
| Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only) | Complete these tabs as instructed. | | |
| Attachments | Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf" | | |
| | Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf" | | |
| | Technical and Lay Abstracts: Upload as Attachment 3 with file name "Abstracts.pdf" | | |
| | Statement of Work: Upload as Attachment 4 with file name "SOW.pdf" | | |
| | Intervention: Upload as Attachment 5 with file name "Intervention.pdf" | | |
| | Human Subject Recruitment and Safety Procedures: Upload as Attachment 6 with file name "HumSubProc.pdf" | | |
| | Data Management: Upload as Attachment 7 with file name "Data_Manage.pdf" | | |
| | Regulatory Strategy: Upload as Attachment 8 with the file name "Regulatory.pdf" | | |
| | Consumer Engagement Statement: Upload as Attachment 9 with the file name "Consumer_Statement.pdf" if applicable | | |
| | Study Personnel and Organization: Upload as Attachment 10 with file name "Personnel.pdf" | | |

| Application Components | Action | Single or Initiating PI Completed | Partnering PI Completed |
|---|---|--|--------------------------------|
| | Questionnaires and Other Research Data Collection Instruments: Upload as Attachment 11 with file name "Data_Collection.pdf" if applicable | | |
| | Transition Plan: Upload as Attachment 12 with file name "Transition.pdf" | | |
| | Impact and Relevance to Military Health Statement: Upload as Attachment 13 with file name "Impact.pdf" | | |
| | Representations (extramural submissions only): Upload as Attachment 14 with file name "RequiredReps.pdf" | | |
| | Suggested Collaborating DOD Military Facility Budget Format: 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 Suggested DOD Military Budget Format, including justification | | |
| Project/Performance Site Location(s) Form | Complete form as instructed | | |

| Application Components | Action | Single or Initiating PI Completed | Partnering PI Completed |
|---|-----------------------------|--|--------------------------------|
| Research & Related Subaward Budget Attachment(s) Form | Complete form as instructed | | |

APPENDIX 1: ACRONYM LIST

| | |
|----------|--|
| ACOS/R&D | Associate Chief of Staff for Research and Development |
| BBRAIN | Boston Biorepository, Recruitment and Integrated Network for GWI |
| CDC | Centers for Disease Control and Prevention |
| CDE | Common Data Elements |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| CTA | Clinical Trial Award |
| CTA-PPIO | Clinical Trial Award – Partnering PI Option |
| DEHP | Di(2-ethylhexyl) Phthalate |
| DHA | Defense Health Agency |
| DMDC | Defense Manpower Data Center |
| DMSS | Defense Medical Surveillance System |
| DOD | Department of Defense |
| DoDGARs | Department of Defense Grant and Agreement Regulations |
| DoDSR | Department of Defense Serum Repository |
| DOEHRs | Defense Occupational and Environmental Health Readiness System |
| DUNS | Data Universal Numbering System |
| eBRAP | Electronic Biomedical Research Application Portal |
| EC | Ethics Committee |
| EMF | Electromagnetic Field |
| ET | Eastern Time |
| FAD | Funding Authorization Document |
| FAPIIS | Federal Awardee Performance and Integrity Information System |
| FDA | U.S. Department of Food and Drug Administration |
| FY | Fiscal Year |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practice |
| GMP | Good Manufacturing Practice |
| GW | Gulf War |
| GWECB | Gulf War Era Cohort and Biorepository |
| GWI | Gulf War Illness |
| GWICTIC | Gulf War Illness Clinical Trials and Interventions Consortium |
| GWIRP | Gulf War Illness Research Program |
| GWVIB | Gulf War Veterans’ Illness Biorepository Brain Bank |

| | |
|---------|---|
| ICH E6 | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| IDE | Investigational Device Exemption |
| IIRA | Investigator-Initiated Research Award |
| ILER | Individual Longitudinal Exposure Record |
| IND | Investigational New Drug |
| IOM | Institute of Medicine |
| IRB | Institutional Review Board |
| LAR | Legally Authorized Representative |
| LOI | Letter of Intent |
| M | Million |
| MAVERIC | Massachusetts Veterans Epidemiology Research and Information Center |
| MB | Megabytes |
| MIPR | Military Interdepartmental Purchase Request |
| MVP | The Million Veteran Program |
| NAM | New Approach Methodology |
| NIH | National Institutes of Health |
| OHARO | Office of Human and Animal Research Oversight (previously Office of Research Protections) |
| OHRO | Office of Human Research Oversight (previously Human Research Protection Office) |
| ORCID | Open Researcher and Contributor ID, Inc. |
| PAH | Polycyclic Aromatic Hydrocarbon |
| PDF | Portable Document Format\ |
| PFAS | Perfluoroalkyl and Polyfluoroalkyl Substances |
| PHS | Public Health Service |
| PI | Principal Investigator |
| PM | Particulate Matter |
| SAM | System for Award Management |
| SOW | Statement of Work |
| STEM | Science, Technology, Engineering, and/or Mathematics |
| TERP | Toxic Exposures Research Program |
| TRA | Translational Research Award |
| UEI | Unique Entity Identifier |
| URL | Uniform Resource Locator |
| USAMRAA | U.S. Army Medical Research Acquisition Activity |
| USAMRDC | U.S. Army Medical Research and Development Command |

USC
VA

United States Code
Department of Veterans Affairs