Program Announcement for the Department of Defense
Defense Health Program

Toxic Exposures Research Program Clinical Trial Partnership Award

Funding Opportunity Number: HT942525TERPCTPA

Pre-Application Due: July 29, 2025

Application Due: October 16, 2025

This program announcement must be read in conjunction with the General Application Instructions, version CD25_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org, and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read the funding opportunity announcement in the order it is written before beginning to prepare application materials**. It is the responsibility of the applicant to determine whether the proposed research meets the intent of the funding opportunity and that all parties meet eligibility requirements.
- Refer to the fiscal year 2025 (FY25) Congressionally Directed Medical Research Programs' (CDMRP) Frequently Asked Questions document for answers to common inquiries regarding the funding opportunity announcements and application process.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Contact Center

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

Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing Alt + left arrow key (Windows) or command + left arrow key (Macintosh) on your keyboard.

1. Basic Information About the Funding Opportunity

Summary: The intent of the FY25 Toxic Exposures Research Program (TERP) Clinical Trial Partnership Award (CTPA) is to support new or existing collaborative partnerships that will rapidly implement 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 military-related toxic exposures. Proposed projects may range from small proof-of-concept clinical trials (e.g., pilot, first-in-human, phase 0) designed to demonstrate the feasibility or inform the design of more advanced trials through large-scale trials (including pragmatic clinical trials) to determine efficacy in relevant patient populations.

Distinctive Features: To encourage applications that include meaningful and productive collaborations between investigators, the FY25 TERP CTPA **requires partnership** of the Initiating Principal Investigator (PI) with at least one, and up to two, other collaborating PIs for the completion of one overarching study.

Funding Details: The CDMRP expects to allot approximately $4.2 million (M) to fund approximately one Clinical Trial Partnership Award application with a total cost cap of $4.2M. The maximum period of performance is 4 years. It is anticipated that the award made from this FY25 funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern Time (ET), July 29 2025
- **Invitation to Submit an Application:** September 4, 2025
- **Application Submission Deadline:** 11:59 p.m. ET, October 16, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, October 21, 2025
- **Peer Review:** December 2025
- **Programmatic Review:** February 2026

Announcement Type: Initial

Funding Opportunity Number: HT942525TERPCTPA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural organizations are eligible to apply***, including foreign and domestic organizations, for-profit and non-profit organizations, and public or private entities***.

Extramural Organization: An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

2.1.2. Principal Investigator

Independent investigators at all career levels may be named by their organizations as the Initiating PI or Partnering PI(s) on the application.

Individuals in a mentored position (e.g. postdoctoral fellows, clinical fellow) are not considered independent investigators.

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

Individuals affiliated with an eligible organization are eligible to be named as PI regardless of ethnicity, nationality, or citizenship status.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the TERP. Congress initiated the TERP in FY22 to provide solutions toward the prevention, diagnosis, treatment and mechanistic understanding of the adverse health outcomes associated with a broad range of military-related toxic exposures. Appropriations for the TERP from FY22 through FY24 totaled $90M. The FY25 appropriation is $15M.

The vision of the TERP is to prevent, minimize and mitigate the impact of military-related toxic exposures and improve the health and quality of life of those affected. The mission of the TERP is to support impactful research aimed at identifying the cause and understanding the health outcomes, comorbidities and pathological mechanisms associated with military-related toxic exposures to facilitate the prevention, diagnosis and treatment of the visible and invisible diseases and symptoms impacting Service Members, their Families, Veterans and the American public.

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

Applicants are strongly encouraged to review Appendix 2, TERP Definitions, before writing and submitting their application.

Collaboration with DOD and/or U.S. Department of Veterans Affairs (VA) researchers and clinicians is encouraged.

3.1. Award History

The TERP Clinical Trial Award (CTA) mechanism was first offered in FY22 and included a partnering PI option. Since then, 26 CTA applications (representing 49 potential awards) were received, and 5 applications (representing 10 awards) were recommended for funding. In FY25, the TERP CTPA mechanism, which *requires* partnership, is being offered for the first time.

3.2. Intent of the Clinical Trial Partnership Award

The intent of the FY25 TERP CTPA is to support new or existing collaborative partnerships that will rapidly implement 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 military-related toxic exposures.

Proposed projects may range from small proof-of-concept clinical trials (e.g., pilot, first-in-human, phase 0) designed to demonstrate the feasibility or inform the design of more advanced trials through large-scale trials (including pragmatic clinical 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 U.S. Food and

Drug Administration (FDA) device or drug approval and/or establishment of clinical practice guidelines, as applicable.

3.2.1. TERP Program Goals and Topic Areas

To meet the intent of the award mechanism, applicants to the CTPA are required to address **at least one of the FY25 TERP Program Goals and at least one of the FY25 TERP Topic Areas**. Proposed research may be related to diseases, conditions, or symptoms supported by other CDMRP programs; however, CTPA applications must be relevant to military-related toxic exposures. Selection of the program goal(s) and topic area(s) is the responsibility of the applicant. Selection must be made during the pre-application submission process and addressed in detail in the full application submission.

Program Goals: *The FY25 TERP Program Goals are not listed in order of importance*. Bulleted items are provided for additional context on current program priorities and, while encouraged, they are not required to be specifically addressed by applications.

1. ***Predict and prevent military-related 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.*
    - Adapt or optimize assays/devices to identify military-related exposures across environments that lead to adverse health effects.
    - Adapt or optimize personal monitoring devices to detect and characterize toxic exposures.
    - Advance exposure assessment methodologies, including but not limited to direct-reading, integrated measurements and machine learning.
2. ***Elucidate mechanisms of how military-related 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 full range of effects from military-related environmental and toxic exposures, including but not limited to long-term illnesses such as Gulf War illness (GWI), cancers (including rare cancers), cardiopulmonary and airway conditions, Parkinson's disease and other neurologic disorders, etc.
    - Evaluate the effects of epigenetic and genomic mechanisms on potential long-term outcomes.
    - Identify biological and/or psychosocial variables that can impact disease outcomes.
    - Identify risk factors and/or biological factors that affect responses to toxic exposures.
    - Understand complex, multi-exposure/physiological or non-chemical stressors (e.g., hormonal, sleep disorders, thermal stress) combinations and how exposure impacts outcome.
    - Address the need for preclinical models that capture the adverse outcomes of human toxic exposures.
3. ***Diagnose the effects of military-related toxic exposures,*** *understand the phenotypic, pathological and clinical outcomes associated with short-term and long-term exposures, and predict disease progression*.

- Identify behavioral factors (smoking, substance abuse, etc.), comorbidities, and preexisting medical conditions that may impact exposure outcomes.
- Identify biomarkers of exposure to individual or multiple toxic substances alone or in combination with physiological/non-chemical stressors.
- Develop diagnostic screens/assays/devices for toxic exposures.

4. ***Develop therapeutics, treatments and strategies*** *to minimize symptoms and disease progression associated with military-related toxic exposures*.
   - Evaluate existing therapeutics, treatments and strategies.
   - Advance new therapeutics, treatments and strategies.
5. ***Understand the multigenerational effects of military-related toxic exposures*** *and how they impact those exposed, their partners, and their descendants.*
   - Understand the link between adverse maternal and paternal reproductive outcomes (including birth defects) and military-related toxic exposures.
   - Evaluate the mechanisms of multigenerational effects of military-related toxic exposures.
   - Understand the cumulative effects of military-related toxic exposures with other military stressors on multigenerational outcomes.

Topic Areas: *Topic areas are not listed in order of importance.*

1. Neurotoxin Exposure
2. Gulf War Illness (GWI) and Its Treatment
3. Airborne Hazards and Burn Pits
4. Other Military Service-Related Toxic Exposures in General, Including Prophylactic Medications, Pesticides, Organophosphates, Toxic Industrial Chemicals, Materials, Metals and Minerals

3.2.2. TERP Additional Guidance

Studies focused on the following areas do NOT meet the intent of the FY25 TERP:

- Research data that are classified and/or research in which the anticipated outcomes may be classified or deemed sensitive to national security concerns.
- Chemical warfare agents categorized as fourth-generation agents or non-traditional agents (NTAs).
- Biological Select Agents or Toxins.
- Anomalous Health Incidents, commonly referred to as Havana Syndrome.
- Directed energy weapons.
- Development of medical countermeasures (MCMs) or devices intended to diagnose, detect, prevent or treat the immediate (point of injury) health effects of chemical weapons, biological, radiological or nuclear threats.

- Treatments or therapeutics for the immediate, adverse health effects of any exposure that would be administered in an acute care setting, i.e., role of care (ROC) 1 or ROC 2.
    - In the military health echelon/ROC, this generally refers to ROC 1 and ROC 2 described below:
        - ROC 1: Unit-level medical care, ranging from point of injury through battalion aid station.
        - ROC 2: Advanced trauma management and emergency medical treatment.
        - For more information on the military roles of care, refer to Chapter 2, "Roles of Medical Care (United States)," Emergency War Surgery, Fifth United States Edition, 2018, Borden Institute.

Studies focused on the following areas ARE permitted. *These examples are meant to inform prospective applicants in the context of the above exclusions and do not imply that these research areas are prioritized over any others within the scope of the FY25 TERP Program Goals and FY25 TERP Topic Areas.*

- Evaluation/treatment of long-term or chronic health impacts of traditional chemical weapons, including but not limited to the long-term effects of sub-lethal doses of sarin, soman, and sulfur mustard, and Gulf War illness.
- Other long-term/chronic effects of military-related exposures that would be diagnosed or treated at a ROC 3 (field hospital) or ROC 4 (definitive care; fixed medical treatment facility), or beyond.

3.2.3. Key Elements for the CTPA

Applicants are strongly encouraged to provide sufficient evidence that demonstrates:

- **Study Design:**
    - Availability of, and access to, appropriate and well justified study population(s) and the proposed intervention.
    - A study team with experience and expertise in all aspects of conducting clinical trials, including statistical analysis, knowledge of regulatory processes (if applicable), study coordination, and data management.
    - Plans for appropriate statistical considerations, data management, analysis and interpretation.
- **Clinical Impact:** Applications should explain how the proposed research will have a significant impact on patient care for Service Members, their Families, Veterans and/or the American public that have been or could potentially be impacted by the effects of military-related toxic exposures. Applications should demonstrate the short- and long-term impacts for how the successful completion of the proposed research will ultimately lead to new treatments/therapeutics/interventions and/or new outcomes (intellectual knowledge or clinical practice guidelines) to improve patient care and/or quality of life for those that have been impacted by or are likely to encounter toxic substances.
- **Partnership:** In order to encourage applications that include meaningful and productive collaborations between investigators, the FY25 TERP CTPA ***requires partnership*** of the Initiating PI with at least one, and up to two, other collaborating PIs for the completion of one overarching study. Each PI is expected to bring a distinct contribution to the application, and

the PIs' unique expertise, when combined as a partnership, should address the research question better than any one investigator could individually. The PIs should have appropriately balanced intellectual input into the design and conduct of the project.

One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. ***The other PI(s) will be identified as Partnering PI(s)***. All PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI(s), refer to Section 5.3, Submission Instructions.

- **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. Any unpublished preliminary data provided should originate from the laboratory of the Initiating and/or Partnering PI(s) and/or a member(s) of the research team.

3.2.4. Other Important Considerations for the CTPA

- ***Funding from this award mechanism must support a clinical trial and may not propose animal or other preclinical research studies.*** A clinical trial is defined in the Code of Federal Regulations, Title 32, Part 219 (32 CFR 219) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. An ***intervention*** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

  Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials. Additionally, studies that solely propose to retrospectively analyze data generated from previously conducted clinical trial(s) are not considered clinical trials.

  Applicants seeking funding for research that does not meet the definition of a clinical trial should consider other FY25 TERP funding opportunities that may be more appropriate for such research. 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 requested will not be recommended for funding.

- **Clinical Trial Start Date and Regulatory Agency Submission:** 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 studies regulated by the Regulatory Agency. Unless otherwise noted, for the purposes of this funding opportunity, Regulatory Agency refers to the FDA or any equivalent international regulatory agency.

  If an Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or equivalent, is required, a regulatory application ***must be submitted to the relevant Regulatory Agency within 6 months of the award date***. The regulatory application should be specific for the product and indication to be tested in the proposed clinical trial.

- **Study Population Considerations:** The recruitment of relevant military and/or Veteran population(s) for the proposed clinical trial(s) is strongly encouraged. Applications not using military and/or Veteran populations for the proposed studies are strongly encouraged to provide justification for how the chosen population(s) is relevant to military-related toxic exposures and will benefit Service Members, their Families, and/or Veterans.
- **Research Team Considerations:** Inclusion of at least one clinician on the study team is strongly encouraged and may be necessary for specific interventions.

  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 FY25 TERP, a consumer is a person living with a disease, injury, or condition or a family member or caregiver of a person impacted by a disease/injury/condition associated with military-related toxic exposures. 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.
- **Rigorous Study Design:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, Nature 490:187-191. While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.
- **Use of DOD or VA Resources:** Applications including investigators within the DOD and applications involving multidisciplinary collaborations among academia, industry, the DOD, the VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, their Families, and/or Veterans. If the proposed research relies on access to unique 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.

Resources for Data and/or Previously Collected Biospecimens

Appendix 3 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 facilitate access to any of these resources and/or control the information presented on the websites listed in Appendix 3.

3.3. CDMRP-wide Encouragements

The following encouragements are broadly applicable across many CDMRP programs, including the TERP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research and meets the intent of this funding opportunity.

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

3.4. Funding Instrument

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

3.5. Funding Details

Period of Performance: The maximum period of performance is **4** years.

Cost Cap: The combined total costs budgeted for the entire period of performance in the applications of the Initiating PI and each Partnering PI should not exceed **$4.2M**. 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.

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 direct costs of the primary award.

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

The appropriateness of the budget for the proposed research will be assessed during peer review.

Direct Cost Restrictions: For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Travel for one investigator from each partnering application to attend one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information and/or disseminate project results from the FY25 TERP CTPA.
- Research subject compensation and reimbursement for study-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving, and resources/equipment to enable participation).

Must not be requested for:

- Travel to scientific/technical meeting(s) beyond the limits stated above.
- Preclinical or animal research.

4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOD organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

Note: Upload documents as individual PDF files unless otherwise noted.

- **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

  - **Background/Rationale:**
    - State the hypothesis of the proposed study and provide a brief explanation of the study rationale clearly articulating how the hypothesis and rationale are well-supported/justified.
    - Specify the intervention to be investigated and indicate the phase of the study and/or class of device, as appropriate.
  - **Specific Aims and Study Design:**
    - Concisely state the specific aims of the proposed clinical trial and briefly describe the scientific approach to address them. Include a description of controls, as appropriate.
    - Briefly describe the study population. The recruitment of relevant military and/or Veteran population(s) for the proposed clinical trial(s) is strongly encouraged. Applications not using military and/or Veteran populations for the proposed studies are strongly encouraged to provide justification for how the chosen population(s) is relevant to military-related toxic exposures and will benefit Service Members, their Families, and/or Veterans.
    - Briefly describe the feasibility of the study including access to patient population(s), plans for recruitment and retention, and how the study will be completed within the proposed period of performance.

- **Alignment:**
  - Describe how the proposed project addresses at least one FY25 TERP Program Goal and at least one FY25 TERP Topic Area.
- **Clinical Impact and Relevance to Military Health:**
  - State both the short- and long-term impacts and how the successful completion of the proposed research will ultimately lead to new treatments/ therapeutics/interventions and/or new outcomes (intellectual knowledge or clinical practice guidelines) to improve patient care and the quality of life for those that have been impacted by, or are likely to encounter, toxic substances.
  - State how the proposed research is responsive to the health care needs of Service Members, their Families, and/or Veterans that have been or could potentially be exposed to military-related toxic exposures.
  - Describe how research findings could also benefit the general population.
- **Partnership:**
  - Briefly describe the partnership and how the collaborative efforts will better address the research question.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:
  - **References Cited (one-page limit):** List the references cited (including URLs, if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
  - **Key Personnel Biographical Sketches: *All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

4.3. Step 2: Full Application Components

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. The application submission process for each Partnering PI uses an abbreviated full application package.

Applicants **must** receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

4.3.1. Full Application Components for the Initiating PI

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov Submissions Only)* Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

IMPORTANT: When completing the SF424 R&R, enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier.

(b) Attachments:

Each attachment of 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 2.

- **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 that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  Describe the proposed project in detail using the outline below. It should be clear from this description that the proposed study meets the definition of a clinical trial. ***Funding from this award mechanism must support a clinical trial and cannot be used for animal or other preclinical research studies.***

  - **Background:** Describe in detail the scientific rationale for the study. Provide a review and analysis of the available literature.
    - Describe the preliminary studies and published or unpublished clinical or preclinical data (required) that support the proposed clinical trial. Any unpublished preliminary data provided should originate from the laboratory of the Initiating and/or Partnering PI(s) and/or a member(s) of the research team.
    - Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.
    - Provide a summary of other relevant ongoing, planned, or completed clinical studies/trials and describe how the proposed trial differs.
    - State the relevance of the proposed research to at least one of the FY25 TERP Program Goals and at least one FY25 TERP Topic Areas.

    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(s) of prior funding. Identify the specific portions of the study that will be supported with funds from this award.

  - **Intervention:** Identify the intervention to be tested. Include the following components, as applicable: intervention type (drug, device, behavioral, surgical, etc.), complete name and composition, source, general concept of design, administration route. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights, along with access to the intervention itself, for conduct of the clinical trial. As applicable, appropriate letters of commitment should be provided in Attachment 2: Supporting Documentation demonstrating the study team's access to the intervention(s) for the

duration of the clinical trial. Describe how the intervention addresses current clinical needs and, if applicable, how it compares with/improves upon currently available interventions and/or standards of care.

- **Objectives/Specific Aims/Hypotheses:** Describe the purpose of the proposed study with detailed objectives. State the hypothesis/research question to be tested in the proposed clinical trial and detail the specific aims that will address the hypothesis/research question. Specific aims outlined here should be the same as those outlined in Attachment 5: Statement of Work. Indicate whether the research addresses health areas and conditions that affect women uniquely, disproportionately, or differently from men.
- **Study Design:** Describe the proposed clinical trial in sufficient detail to evaluate its appropriateness and feasibility, relating to both the scientific success of the study and setting reasonable expectations for what study participants will experience.
  - Describe the type of study to be performed. Outline the proposed clinical trial methodology and study variables in sufficient detail to demonstrate a clear course of action and justification. Describe the interaction with the human subject, including the study intervention that they will experience, and include the dose and administration route. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the study participant will experience.
  - Provide a schedule (e.g., flowchart or diagram) of study intervention(s), evaluation(s), and follow-up procedures, including, if applicable, the biospecimen that will be collected along with the collection schedule and amount. Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions). Define each arm/study group of the proposed trial, if applicable, and describe how group assignment will occur. Include a description of controls, as appropriate. Specify the approximate number of study participants to be enrolled. Indicate whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.
  - Define all endpoints/outcome measures relevant to the objective of the study, explain why they were chosen, and describe how, when, and where they will be measured. Include all evaluations that will be made for study purposes. If questionnaires or other research data collection instruments will be used, include a copy of them within Attachment 2: Supporting Documentation. Describe the reliability and validity of the selected endpoint/outcome measures and evaluations along with the applicable quality standards. Explain how the results of evaluations and/or data collection instruments will be used to meet the objectives of the study (or to monitor safety of human subjects).

    If proposing clinical trials with Gulf War (GW) Veterans, the use of the Common Data Elements (CDEs) for GWI Clinical Research 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.
  - Briefly describe the study population. The recruitment of relevant military and/or Veteran population(s) for the proposed clinical trial(s) is strongly encouraged. Applications not using military or Veteran populations for the proposed studies are strongly encouraged to provide justification for how the chosen population(s)

is relevant to military-related toxic exposures and will benefit Service Members, Veterans, and/or their Families. Additional details should be provided in Attachment 6: Study Population Recruitment and Safety Plan.

- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.
  - Include a complete power analysis to demonstrate that the proposed clinical trial's anticipated sample size is appropriate to meet the objectives of the study. Describe all clinical and statistical justifications and assumptions that support the sample size calculations. Explain any anticipated subgroup analyses and demonstrate that such analyses will be appropriately powered.
  - Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
  - For phase 3 clinical trials, describe plans for the valid and sufficiently powered analysis of group differences on the basis on sex, race, and/or ethnicity as appropriate for the scientific goals of the study. Refer to the CDMRP directive on the Inclusion of Women and Minorities as Subjects in Clinical Research for additional information on the requirements for phase 3 studies.
- **Pitfalls and Mitigation Strategy:** Describe potential challenges and discuss alternative methods/approaches that may be employed to overcome them.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. 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.
  - **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 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 Support (two-page limit per letter *is recommended*):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work for the duration of the proposed clinical trial. As applicable, provide appropriate letters of commitment demonstrating the study team's access to the intervention(s) for the duration of the clinical trial. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support signed by any consumer(s) participating on the research team to demonstrate their commitment to the proposed project. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.
- **Data and Research Resources Sharing Plan:** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe how data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical trial participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study. Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.
- **Questionnaires and Other Research Data Collection Instruments *(if applicable)*:** Include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides, or other instruments. This should include any drafts that are currently in use or underdevelopment.
- **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.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

- **Background:** Present the scientific rationale and reasoning behind the proposed clinical trial.
- **Hypothesis/Objective(s):** State the hypothesis/research question to be tested and the objectives to be reached.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Provide a brief statement on the type and phase of the trial to be conducted, the intervention being studied, and the primary projected outcomes of the study. Briefly describe the study design, including appropriate controls.
- **Clinical Impact:** Briefly describe how the proposed research will have a significant impact on patient care for Service Members, their Families, Veterans, and/or the American public that have been, or could potentially be, impacted by the effects of military-related toxic exposures. State both the short- and long-term impacts and how the proposed research will ultimately lead to new treatments/therapeutics/interventions and/or new outcomes (intellectual knowledge or clinical practice guidelines) 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 FY25 TERP Program Goals and addresses at least one of the FY25 TERP Topic Areas.
- **Relevance to Military Health:** State how the proposed research is responsive to the health care needs of Service Members, their Families, and/or Veterans that have been or could potentially be exposed to military-related toxic exposures. Describe how research findings could also benefit the general population.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse of scientific jargon, acronyms, and abbreviations.

  - Clearly describe the objectives and rationale for the proposed study and intervention.
  - 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 FY25 TERP Program Goals and at least one of the FY25 TERP Topic Areas.
    - What types of patients will it help and how will it help them?
    - What are the potential clinical applications and short- and long-term benefits?
    - How is the proposed intervention expected to improve patient care and/or quality of life?
  - What is the projected timeline it may take to achieve an impact on the standard of care for adverse health outcomes associated with military-related toxic exposures?

- **Attachment 5: Statement of Work (seven-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the "Suggested SOW Format."

  Guidance for preparing the SOW for the CTPA can be found in the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work."

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

  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/subaward 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.
  - Indicate timelines required for regulatory approvals relevant to human subjects research (e.g., local Institutional Review Board [IRB] and federal USAMRDC Office of Human and Animal Research Oversight [OHARO] approvals, IND and IDE applications, as applicable). Refer to the General Application Instructions, Appendix 6, 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.

- **Attachment 6: Study Population Recruitment and Safety Plan (no page limit): Upload as "StudyPopPlan.pdf".** Include the components listed below.

  - **Enrollment Distribution:** Provide anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report. The enrollment table(s) should be appropriate to the objectives of the study.
  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. If limiting inclusion by age, race, ethnicity or sex, provide strong rationale based on justification from scientific literature, preliminary data, or other relevant considerations. 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. Describe how the study population represents the population anticipated to benefit from the intervention.
  - ***The recruitment of relevant military and/or Veteran population(s) for the proposed clinical trial(s) is strongly encouraged. Applications not using military or Veteran populations for the proposed studies are strongly encouraged to provide justification for how the chosen population(s) is relevant to military-related toxic exposures and will benefit Service Members, Veterans, and/or their Families.***

- For studies involving GW Veterans, the use of both the U.S. Centers for Disease Control and Prevention (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.
- **Study Population Availability:** Demonstrate that the research team has access to the proposed study population at each site. Discuss the team's past efforts in recruiting human subjects from the target population for previous clinical trials/research, if applicable. Describe the approximate number, pertinent demographic information, and other relevant characteristics of the study population at each enrollment site. Indicate whether the actual size of available study population may be affected by ongoing clinical trials that compete for the same population. If the proposed research involves access to military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding, or other agreements required to access and publish data. Refer to the General Application Instructions, Appendix 4, for additional considerations.
- **Recruitment and Retention Process:** Explain methods for identification of potential study participants (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail. Address who will identify potential study participants, who will recruit them, and what methods will be used to recruit them. Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study. If study participants will be compensated, include a detailed description of and justification for the compensation plan. Describe the methods that will be employed to retain participants within the study. Discuss past efforts in recruiting and retaining study participants for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Estimate the potential for participant loss to follow-up and how such loss will be handled/mitigated. Indicate whether the study team has considered barriers to clinical trial participation and, if applicable, how the team aims to mitigate or overcome these barriers.
- **Women and Minorities Recruitment/Retention Strategy:** Describe the strategy for recruitment and retention specific to women and minorities in the clinical trial appropriate to the objectives of the study.
- **Informed Consent Process:** Specifically describe the plan for obtaining informed consent from study participants. Include information regarding the timing and location of the consent process. If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, describe the plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent. Appendix 6 of the General Application Instructions contains additional considerations unique to DOD-sponsored research.
- **Risks/Benefits Assessment:**
  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. 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). 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 Regulatory Agency (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. 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.
- **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: 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 a Regulatory Agency:

  – Provide evidence that the clinical trial does not require regulation by a Regulatory Agency. Submissions providing "not applicable," "none," or similar responses do not satisfy this request. No further information for this attachment is required.

  For products that require regulation by a Regulatory Agency:

  – Describe the overall regulatory strategy and product development plan that will be performed during the project's period of performance to support the planned product indication/label. Include, as appropriate, a description of the numbers and types of studies proposed to reach approval, licensure, or clearance; the types of Regulatory Agency meetings that will be held/planned; and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines.

    - State whether the product is FDA-approved, -licensed or -cleared, and marketed in the United States. If the product is marketed in the United States, state the product label indication and whether the proposed research involves a change to the approved label indication.
    - If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use and whether an IND or IDE application was submitted. ***If an IND or IDE is required, the application must be submitted to the FDA within 6 months of the award date.*** 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. Describe the current status of the application, and if the IND or IDE application has been placed on clinical or partial hold, explain the conditions that must be met to release the hold.

- Provide a summary of any meetings the research team had with regulatory agencies or consultants regarding the proposed research. Include key outcomes, action items, and recommendations. If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
- If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).

- **Attachment 8: Partnership, Personnel, and Study Management (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.
  - **Partnership:** Describe the partnership, including how the combined unique expertise of the Initiating and Partnering PI(s) will better address the research question and why the work should be done together rather than through separate individual efforts. Explain how all PIs have an appropriately balanced intellectual input into the design of the project.
  - **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, including the location of the organization. If applicable, identify the Regulatory Agency sponsor and any external consultants or other experts who will assist with Regulatory Agency sponsor applications. While there is no specified format for this information, a table(s) or diagram is recommended.
  - **Study Personnel Description:** Describe the composition, background, and qualifications of the study team in enough detail to determine whether the team includes relevant subject matter expertise (e.g., statistical, disease/condition, clinical study, or regulatory expertise) to accomplish the proposed work. Include the roles of individuals named in the organizational chart along with any external consultants or advisors who will provide critical guidance and input to the study team (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate). Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed clinical trial.

    The inclusion of at least one clinician on the study team is strongly encouraged and may be necessary for specific interventions.

    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.

    If a military or Veteran consumer will be a member of the research team, describe how they will contribute to the development of the research question, project design, oversight and evaluation, as well as any other significant aspects of the proposed project.

- **Study Management Plan:** Describe the day-to-day management of the proposed clinical trial. 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. If applicable, describe how communication and data transfer between/among the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared. Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Attachment 9: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".** Discuss the anticipated methods and strategies necessary to move the anticipated research outcome (e.g., intervention, product, methodology, finding) to the next phase of development (e.g., clinical trials, commercialization, and/or delivery to the civilian or military market), assuming a positive outcome from the proposed clinical trial. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. Applicants are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development when preparing the transition plan. ***The post-award transition plan should:***
  - Name the project's anticipated research outcomes including knowledge products and/or clinical products for development. A "knowledge product" is a non-materiel product that aims to transition into medical practice, training, tools, or to support materiel solutions; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes. Describe how the anticipated outcomes/products will be disseminated to both the scientific and consumer/stakeholder communities.
  - Include a timeline with defined milestones describing the logical next steps to advance the research outcome to the subsequent stage of development (e.g., further research, next-phase clinical trials, commercialization/transition to industry, delivery to the military or civilian market, incorporation into clinical practice, and/or clearance/approval by a Regulatory Agency).
  - Describe collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) that are in place or will be established to execute the steps described above.
  - Include a discussion of the funding strategy necessary to transition the research outcome to the next level of investigation, development, and/or commercialization. This may include commercial sponsorship, venture capital, federal or non-federal funding opportunities, etc.
  - As appropriate, discuss ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award. Include a plan for resolving intellectual and material property issues among participating organizations. If the intellectual property rights are not owned by the applicant, PI, or a member of the study team, describe the planned next steps necessary to make the product available to the target population.

- **Attachment 10: Clinical Impact and Relevance to Military Health Statement (three-page limit): Upload as "Impact.pdf".** The impact statement summarizes the potential

short- and long-term impact of the proposed clinical trial. The statement should address the points outlined below written ***in a manner that will be readily understood by readers without a background in science or medicine***.

- Articulate how a successful outcome(s) of the proposed clinical trial will advance at least one of the FY25 TERP Program Goals and at least one of the FY25 TERP Topic Areas.
- Describe 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 the anticipated short-term benefits for individuals impacted by military-related toxic exposures.
- Explain the anticipated long-term impacts of how implementing the intervention and disseminating the study outcomes will improve patient care and/or quality of life for Service Members, their Families, Veterans, and/or the American public.
- If applicable, describe how the intervention represents an improvement over currently available interventions and/or standards of care.
- Describe any relevant controversies or treatment issues that will be addressed by the proposed clinical trial.
- Describe any limitations to the impact of the proposed clinical trial, even if the study is successful.
- Describe how the proposed effort is responsive to the health care needs and quality of life of Service Members, their Families, and/or Veterans.
- 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.
- If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- If applicable, indicate to what extent the project findings are anticipated to lead to improvements in women's health outcomes and/or advancements in knowledge for women's health.

- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or

execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

- **Biographical Sketch:** Upload as "Biosketch_LastName.pdf".

  The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.

  Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).

- **Current/Pending Support:** Upload as "Support_LastName.pdf".

  Current and pending (other) support information are used to assess the capacity or any conflicts of commitment that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.

  Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for NIH or NSF.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

- **Budget Justification (no page limit):** For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.
- ***Initiating and Partnering PI(s) must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed information.***

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions only)*: Refer to the General Application Instructions, Section IV.C.(e), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.

- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf".

4.3.2. Full Application Components for Each Partnering PI

Refer to the equivalent attachment above for details specific to each of the following application components. See Appendix 1 for a checklist of the full application components required for each Partnering PI.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

NOTE: Enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier Box

(b) Attachments:

- **Attachment 5: Statement of Work (seven-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and Senior/Key Person's current/pending support information must be attached to the individual's Profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

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

Initiating and Partnering PI(s) must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI(s) should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed information.

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions Only)*: Refer to the General Application Instructions, Section IV.C.(e), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf".

4.4. Other Application Elements

- If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.
- The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525TERPCTPA from Grants.gov or eBRAP, depending on which submission portal will be used.

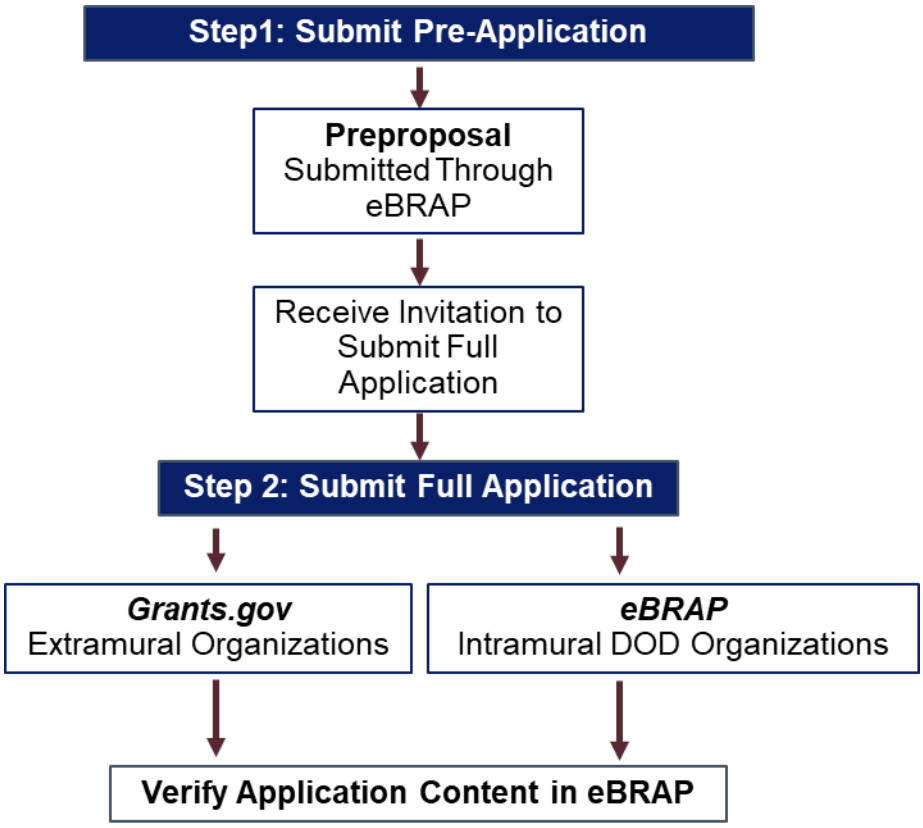
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration. More information regarding SAM registration can be found in the General Application Instructions, Section IV.A.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions.

Application Submission Workflow



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the Initiating PI through eBRAP, including the submission of contact information for each Partnering PI.

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

After the Initiating PI confirms submission of the pre-application, the Partnering PI(s) will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI(s) must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.***

Partnering PI(s) should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

- The Partnering PI(s) will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Partnering PI(s) will not be able to submit their full application package components to eBRAP.

Refer to the General Application Instructions, Section III.B, for considerations and detailed instructions regarding pre-application submission.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding Grants.gov submissions.

eBRAP Submissions: Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the “Full Application Files” tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all

application components and ensure the proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted through the appropriate portal prior to the full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant.***

All submission dates and times are indicated in Section 1, Basic Information above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

Submitting applications that 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).

While it is allowable to propose similar research projects to different programs within CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's full position on research duplication.

Including classified research data within the application and/or proposing research that may produce classified outcomes or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

Members of the FY25 TERP Programmatic Panel should not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment, and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY25 TERP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the TERP, pre-applications will be screened based on the following criteria:

- **Background and Rationale**
  - Whether the study rationale and hypothesis are well supported and justified.
- **Specific Aims and Study Design**
  - Whether the specific aims are clearly stated and how well they support the scientific approach.
  - To what degree the proposed study population is appropriate for the proposed clinical trial and whether the study is feasible.
- **Alignment**
  - How well the proposed project addresses at least one of the FY25 TERP Program Goals and at least one of the FY25 TERP Topic Areas.
  - Whether the proposed project adheres to the intent of the FY25 TERP and is compliant with the program's Additional Guidance.

- **Clinical Impact and Relevance to Military Health**
  - To what degree the proposed research project will have both short- and long-term impacts and the successful completion of the project will ultimately lead to new treatments/therapeutics/interventions and/or new outcomes (intellectual knowledge or clinical practice guidelines) to improve patient care and the quality of life for those that have been impacted by or are likely to encounter toxic substances.
  - To what degree the proposed research is responsive to the health care needs of Service Members, their Families, and/or Veterans that have been or could potentially be exposed to military-related toxic exposures.
  - To what extent the research findings could benefit the general population.
- **Partnership**
  - How well the proposed study describes the partnership and how the collaborative efforts will better address the research question.

6.2.2. Peer Review Criteria

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

- **Clinical Impact and Relevance to Military Health**
  - To what extent a successful outcome(s) of the proposed clinical trial will advance at least one of the FY25 TERP Program Goals and at least one of the FY25 TERP Topic Areas.
  - How well the short-term impacts including the anticipated outcomes/products (intellectual knowledge 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.
  - To what degree the anticipated long-term impacts of implementing the intervention and disseminating the study outcomes will improve patient care and/or quality of life for Service Members, their Families, Veterans, and/or the American public.
  - Whether the application describes any limitations to the impact of the proposed clinical trial, even if the study is successful.
  - Whether the proposed effort is responsive to the health care needs and quality of life of Service Members, their Families, and/or Veterans.
  - 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 the civilian population and address a military need, as appropriate.
  - If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- **Research Strategy and Feasibility**
  - How well the scientific rationale for the proposed clinical trial is supported by preliminary (published or unpublished clinical or preclinical) data, and review and analysis of the available literature and ongoing/completed studies.
  - Whether the hypothesis/objectives are clearly stated and how well the detailed specific aims are described and align with the tasks in the SOW.

- How well the specific aims/hypotheses/research question, study design, experimental methods, data collection procedures, and evaluations are designed to address the clinical objective and purpose of the study.
- To what degree the planned route and schedule of study intervention(s), evaluations(s), and follow-up procedures is reasonable for study participants to experience.
- Whether there is evidence indicating access to the intervention from its source, for the duration of the proposed clinical trial (if applicable).
- How well potential challenges and alternative strategies are discussed.

- **Recruitment, Accrual, Retention**
  - To what degree the plan for recruiting, enrolling, and retaining study participants is reasonable to meet the needs of the proposed clinical trial.
  - Whether there is sufficient evidence that the research team has access to the proposed study population at each site and if applicable, describes the team's past efforts in recruiting human subjects from the target population.
  - How well the application identifies possible delays (e.g., slow/low enrollment, poor retention) and presents adequate mitigation plans to resolve them.
  - To what degree the number of study participants to be enrolled is reasonable based upon the proposed timeline, study procedures, available study population, inclusion/exclusion criteria, and planned efforts to achieve accrual goals.
  - Whether the distribution of the proposed enrollment on the basis of age, sex, race, and/or ethnicity is appropriate for the proposed research.
  - If applicable, whether the justification for limiting inclusion of any demographic group, including sex, is sufficiently strong.
  - To what extent the strategy for recruitment and retention of women and minorities in the clinical trial is appropriate to the objectives of the study.
  - If applicable, whether studies including GW Veterans use both the CDC and Kansas case definitions and whether any additional case definitions of GWI are justified and well-defined for the study.
- **Regulatory Strategy and Post-Award Transition Plan**
  - To what extent the regulatory strategy and product development plan are well described and appropriate to support the product indication or product label change, if applicable.
  - Whether the application includes documentation that the study is exempt from regulatory agency oversight, or that the IND or IDE application (and/or international equivalent) can feasibly be submitted within 6 months of award, as appropriate.
  - How well the documentation provided supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) covering the proposed trial, if applicable.
  - Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.
  - To what degree the next logical steps, including timeline, milestones and funding strategy, are realistic and appropriate to bring the research outcomes/products to the subsequent stage of development/implementation/dissemination after successful completion of the proposed clinical trial.

- How well the application describes the manner by which outcomes/products of the proposed research will be disseminated to both the scientific and consumer/stakeholder communities.
- To what degree the collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) intended to help advance the research outcomes/products are established and/or achievable.
- To what degree ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award are considered and addressed in planning.

- **Statistical Plan and Data Analysis**
  - To what degree the statistical model and data analysis plan are suitable for the planned study objectives.
  - To what degree the sample size projections are adequate to ensure proper power for the study, and as applicable, any subgroup analysis.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study and will be factored into the data analysis plan or whether the justification for a single sex study is sufficiently strong.
  - If a phase 3 trial is proposed, whether the plans for the valid analysis of group differences on the basis of sex, race, and/or ethnicity 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.
  - 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 the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
  - If applicable, to what degree barriers to clinical trial participation have been considered and/or addressed.
- **Partnership, Personnel and Study Management**
  - To what degree the combined unique expertise of the Initiating and Partnering PI(s) will better address the research question together rather than through separate individual efforts.
  - How well the application reflects that all PIs provided an appropriately balanced intellectual input into the design of the project.
  - To what degree the composition, background, and qualifications of the study team, including any external consultants or advisors (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate), are appropriate to accomplish the proposed work.

- Whether the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
- How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures, multi-institutional structure governing the research protocol(s)) are appropriate and meet the needs of the proposed clinical trial.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Data and Research Resources Sharing**
  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable and includes dissemination activities to feed back the data to affected communities and/or study participants. If applicable, whether specific repository(ies) are named where scientific data and resources arising from the project will be archived.
- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **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.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

6.2.3. 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 priorities of the FY25 TERP, as evidenced by the following:
  - Adherence to the intent of the award mechanism.
  - Program portfolio composition and balance.
  - Relative clinical impact and relevance to military health.

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, Initiating PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section 1, Basic Information

About the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

6.3.2. Full Application

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 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer 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.

6.4. Risk, 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 SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. 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.

In accordance with National Security Presidential Memorandum and all associated laws, all fundamental research funded by the DoD must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the application receipt and review process for the TERP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. 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 (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An 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. For additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section.

8. Post-Award Requirements

8.1. 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 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

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. Additionally, the CDMRP requires all funded Applicable Clinical Trials to register on ClinicalTrials.gov. Additional data reporting requirements will also apply to Applicable Clinical Trials supported under this funding opportunity. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC OHARO, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), IRB, or Ethics Committee (EC) review. Refer to the General Application Instructions, Appendix 6, for additional information.

8.2. Reporting

Quarterly technical progress reports and quad charts, annual technical progress reports and quad charts, as well as a final technical progress report and a final quad chart will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

PHS Inclusion Enrollment Reporting Requirement: Enrollment reporting on the basis of sex, race, and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available in eBRAP.

Award Expiration Transition Plan: An Award Expiration Transition Plan, using the template available on eBRAP, must be submitted with the final progress report.

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 SAM 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 8, Section B).

8.3. Additional Requirements

Unless otherwise restricted, changes in the PI (Initiating or Partnering) will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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.

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 7, Section H, for general information on organization or PI changes.

9. Other Information

9.1. 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 CD25_01Te. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

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

9.2.1. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

The following will result in administrative rejection of the full application:

- Submission of an application for which a letter of invitation was not issued.
- Project Narrative is missing.
- Budget is missing.
- Study Population Recruitment and Safety Plan (Attachment 6) is missing.
- Regulatory Strategy (Attachment 7) is missing.
- Partnership, Personnel, and Study Management (Attachment 8) is missing.
- Post-Award Transition Plan (Attachment 9) is missing.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

The following may result in administrative withdrawal of the full application:

- A member of the FY25 TERP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY25, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publications and/or Patents abstract sections.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Failure to submit all associated (Initiating and Partnering PI[s]) applications by the deadline.
- The Initiating PI and/or Partnering PI(s) do not meet the eligibility criteria.
- The invited application proposes a different research project than that described in the pre-application.
- 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 project includes animal or other preclinical research.

9.2.4. 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.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance *(Grants.gov submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(eBRAP submissions only)*	☐	☐
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐	
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐	☐
Study Population Recruitment and Safety Plan – Attachment 6, upload as "StudyPopPlan.pdf"	☐	
Regulatory Strategy – Attachment 7, upload as "Regulatory.pdf"	☐	
Partnership, Personnel, and Study Management – Attachment 8, upload as "Personnel.pdf"	☐	
Post-Award Transition Plan – Attachment 9, upload as "Transition.pdf"	☐	
Clinical Impact and Relevance to Military Health Statement – Attachment 10, upload as "Impact.pdf"	☐	
Representations *(Grants.gov submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach Biographical Sketch for PI and Senior/Key Persons ("Biosketch_LastName.pdf")	☐	☐
Attach Current/Pending Support for PI and Senior/Key Persons ("Support_LastName.pdf")	☐	☐
Budget **Include Budget Justification**	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐	☐

Appendix 2. TERP Definitions

The TERP uses the following definitions:

- **Fourth Generation Agents (FGA):** "Fourth generation agents, also known as Novichoks or A-series nerve agents, belong to a category of chemical warfare agents that are unique organophosphorus compounds. They are more persistent than other nerve agents and are at least as toxic as VX."
- **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." In this report, the IOM recommended the use of both the 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."
    - The former DOD CDMRP GWIRP assembled multiple resources that applicants may find helpful if proposing studies on GWI.
    - **Common Data Elements (CDEs) for GWI Clinical Research:** Through a collaboration among the NIH, CDC, VA, former DOD CDMRP GWIRP, and the GWI community, CDE recommendations were developed for GWI. Applicants proposing clinical research 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 on the GWIRP website 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.
- **Medical Countermeasures (MCMs):** Medicines and medical products that can be used to diagnose, prevent, or treat diseases/conditions/symptoms related to chemical, biological, radiological, or nuclear (CBRN) threats.
- **Military-Related Toxic Exposures:** Exposures to known or unknown, naturally occurring or manmade substances associated with deployed, garrison, or other military-linked environments that result in adverse health effects. For the purposes of this TERP program announcement, exposures solely focused on environmental extremes are not considered military-related toxic exposures.
- **New Approach Methodologies (NAMs):** "Technologies and approaches that can potentially provide the same hazard and risk assessment information without the use of animal testing."
- **Neurotoxin:** Synthetic or natural substances that damage, destroy, or impair the functioning of the nervous system.
- **Non-Traditional Agents (NTAs):** "Novel chemical threat agents or toxicants requiring adapted countermeasures."

- **Roles of Medical Care:** "The characterization of health support for the distribution of medical resources and capabilities." For more information on the military roles of care, refer to Chapter 2, "Roles of Medical Care (United States)," Emergency War Surgery, Fifth United States Edition, 2018, Borden Institute.
- **Toxicant:** "A poison that is made by humans or that is put into the environment by human activities."
- **Toxic Exposures:** Exposures to known and unknown naturally occurring or manmade, harmful substances that result in adverse health effects.

Appendix 3. Resources for Data and/or Previously Collected Biospecimens

Boston Biorepository, Recruitment, and Integrated Network for GWI (BBRAIN)
Defense Health Agency (DHA) Data Sharing Agreements
Defense Manpower Data Center (DMDC)
Defense Medical Surveillance System (DMSS)
Defense Occupational and Environmental Health Readiness System (DOEHRS)
DOD Serum Repository (DODSR)
Gulf War Illness Clinical Trials and Interventions Consortium (GWICTIC)
Individual Longitudinal Exposure Record (ILER)
Massachusetts Veterans Epidemiology Research and Information Collaborative (MAVERIC)
Millennium Cohort Study
Million Veteran Program (MVP)
VA Environmental Health Registries
VA Gulf War Veterans' Illnesses Biorepository Brain Bank (GWVIB)
VA Gulf War Era Cohort and Biorepository (GWECB)

Appendix 4. Acronym List

BBRAIN	Boston Biorepository, Recruitment, and Integrated Network for GWI
CDC	U.S. Centers for Disease Control and Prevention
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CTPA	Clinical Trial Partnership Award
DHA	Defense Health Agency
DMDC	Defense Manpower Data Center
DMSS	Defense Medical Surveillance System
DOD	U.S. 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
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FGA	Fourth Generation Agent
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' Illnesses Biorepository Brain Bank
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
ILER	Individual Longitudinal Exposure Record
IND	Investigational New Drug
IOM	Institute of Medicine
IRB	Institutional Review Board
M	Million

MAVERIC	Massachusetts Veterans Epidemiology Research and Information Collaborative
MCM	Medical Countermeasure
MIPR	Military Interdepartmental Purchase Request
MVP	Million Veteran Program
NAMs	New Approach Methodologies
NIH	National Institutes of Health
NSF	U.S. National Science Foundation
NTA	Non-Traditional Agent
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
ROC	Roles of Care; Role of Care
RPPR	Research Performance Progress Report
SAM	System for Award Management
SciENcv	Science Experts Network Curriculum Vitae
SF424	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TERP	Toxic Exposures Research Program
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	United States Code
VA	U.S. Department of Veterans Affairs