Program Announcement for the Defense Health Agency

Toxic Exposures Research Program Clinical Trial Award

Funding Opportunity Number: HT942526TERPCTA

Pre-Application Due: August 19, 2026

Application Due: November 19, 2026

This program announcement must be read in conjunction with the General Application Instructions, version CD26_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 this 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 this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the 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 Support 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 the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

Click ⓘ to be taken to additional guidance and instructions within the General Application Instructions (GAI).

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Toxic Exposures Research Program (TERP) Clinical Trial Award (CTA) mechanism supports the advancement, execution, and analysis of clinical trials with the potential to have a significant impact on the prevention, treatment, or management of symptoms, diseases or conditions associated with or resulting from 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, the FY26 TERP CTA includes a **Partnering Principal Investigator Option (PPIO)**. One Principal Investigator (PI) is identified as the initiating PI, and an additional PI may be identified as a Partnering PI. If recommended for funding, each PI will be named on separate awards. The intent is to support interdisciplinary partnerships, such as those between clinicians and research scientists, that will accelerate the movement of promising interventions/knowledge products into clinical applications. Partnering should significantly advance the research beyond what would be possible through independent efforts.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $4.5M to fund approximately one Clinical Trial Award application with total cost caps of $4.5M per award. The maximum period of performance is 4 years. It is anticipated that awards made from this fiscal year 2026 (FY26) funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), August 19, 2026
- **Invitation to Submit an Application:** October 1, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, November 19, 2026
- **End of Application Verification Period:** 5:00 p.m. ET November 24, 2026
- **Peer Review:** January 2027
- **Programmatic Review:** March 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526TERPCTA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities*.**

2.1.2. Principal Investigator

Independent investigators at all career levels may be named by their organizations as the Principal Investigator (PI) or the partnering PI on the application.

Partnering PI Option (PPIO): One initiating PI and one partnering PI may collaborate on a single application, each of whom will be recognized as a PI and receive a separate award.

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

Independent investigators affiliated with an eligible organization are eligible to be named as the PI or the Partnering PI on the application, regardless of ethnicity, nationality or citizenship status

An investigator may be named on only one TERP application as a PI.

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 GAI for additional recipient qualification requirements.

3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Toxic Exposures Research Program (TERP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. Congress initiated the TERP in 2022 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 FY25 totaled $105 million (M). The FY26 appropriation is $15M.

The vision of the TERP is to improve the health and quality of life and mitigate risks for those impacted by military-related toxic exposures. The mission of the TERP is to fund research to understand and provide solutions to prevent, diagnose, and treat the health outcomes associated with military-related toxic exposures impacting Service Members, Veterans, their Families and the 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.

The TERP strongly encourages applicants to review Appendix 3, TERP Definitions, before writing and submitting their application.

The TERP encourages collaboration with DOW and/or U.S. Department of Veterans Affairs (VA) researchers and clinicians.

3.1. Award History

The TERP Clinical Trial Award mechanism was first offered in FY22, with the Clinical Trial Partnership Award (which required partnership) being offered in FY25. Since FY22, 37 CTA applications (representing 72 potential awards) were received, and six applications (representing 12 awards) were recommended for funding.

3.2. Intent of the Clinical Trial Award

The TERP Clinical Trial Award (CTA) mechanism supports the advancement, execution, and analysis of clinical trials with the potential to have a significant impact on the prevention, treatment or management of symptoms, diseases, or conditions associated with or resulting from military-related toxic exposures.

Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs or biologics), medical devices, clinical guidance, and/or emerging approaches and technologies. Proposed projects may range from small proof-of-concept trials (i.e., pilot, first-in-human, phase 0) to demonstrate the feasibility or inform the design of more advanced trials, through large-scale trials to determine efficacy in relevant patient populations. 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 the 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 CTA are required to address **at least one of the FY26 TERP program goals and at least one of the FY26 TERP topic areas.** The proposed research may be related to diseases, conditions, or symptoms supported by other CDMRP programs; however, CTA 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 FY26 TERP Program Goals are not listed in order of importance*. The bulleted items are provided for additional context on current program priorities and, while encouraged, these are not the only items that can be addressed by applications.

Predict and Prevent: *Identify strategies that can anticipate, identify, monitor, and prevent adverse effects of exposures to toxic substances.*

- Understand the full range of effects from military-related environmental and toxic exposures to aid in predicting/preventing the effects.
- Understand the mechanisms of multigenerational effects of military-related toxic exposures and the impact of these exposures on reproductive health to aid in predicting/preventing the effects.
- Identify biological and/or psychosocial variables and risk factors that can impact disease outcomes from toxic exposures.
- Develop, adapt, validate, or optimize monitoring, for example, personal devices to detect and characterize individual environmental exposures.

Diagnose: *Understand the clinical signs, symptoms, and outcomes associated with exposures; and predict disease progression to develop specific or improved diagnostics.*

- Understand complex, multi-exposure/physiological or nonchemical stressor (e.g., hormonal, sleep disorders, thermal stress) combinations, and how exposure impacts outcome.
- Identify behavioral factors (smoking, substance abuse, etc.), comorbidities, and pre-existing medical conditions that may impact exposure outcomes.
- Identify biomarkers of exposure to individual or multiple toxic substances alone or in combination with physiological/nonchemical stressors.
- Develop diagnostic screens/assays/devices for toxic exposures.

Treat: *Minimize symptoms and disease progression associated with exposures.*

- Develop new or improve existing therapeutics, treatments and strategies.
- Advance new therapeutics, treatments and strategies.
- Address the need for preclinical models that capture the adverse outcomes of human toxic exposures.

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

- Neurotoxin Exposure
- Gulf War Illness (GWI) and Its Treatment
- Airborne Hazards and Burn Pits

- Other Military Service-Related Toxic Exposures in General, including Prophylactic Medications, Groundwater Contamination, 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 FY26 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.
- Biological Select Agents or Toxins.
- Anomalous Health Incidents, commonly referred to as Havana Syndrome.
- Directed energy weapons.
- Development of medical countermeasures 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 FY26 TERP Program Goals and FY26 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 CTA

- **Study Design:** Applications should demonstrate the availability of, and access to, appropriate and well-justified study population(s) and the proposed intervention. Applications should describe 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. Applications should include plans for

appropriate statistical considerations, data management, analysis and interpretation. ***Applicants are strongly encouraged to utilize objective data and measures to the maximum extent practicable.***

- **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 how the successful completion of the proposed research will have short- and long-term impacts, ultimately leading to new treatments/therapeutics/interventions and/or new outcomes (intellectual knowledge or clinical practice guidelines) that improve patient care and/or quality of life for those impacted by or likely to encounter toxic substances.
- **Preliminary Data are Required:** Applications must include preliminary data relevant to the proposed clinical trial. The proposed clinical trial must be based on a sound scientific rationale that is established through logical reasoning and critical review and analysis of the relevant literature. Any unpublished preliminary data provided should originate from the laboratory of the PI(s) and/or member(s) of the research team.
- **Partnering PI Option:** The CTA includes an option for the Initiating PI to collaborate with one partnering PI in order to encourage applications that include meaningful and productive collaborations between investigators. The intent of this option is to support new or existing interdisciplinary partnerships, such as those between clinicians and research scientists that will accelerate the movement of promising interventions/knowledge products into clinical applications.

  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 will be identified as a Partnering PI. 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. 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, refer to Section 5.3, Submission Instructions.

3.2.4. Other Important Considerations for the CTA

Funding from this award mechanism must support a clinical trial. Preclinical and animal research is not supported in this funding opportunity.

Applicants seeking funding for research that does not meet the definition of a clinical trial should consider other FY26 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. CTA applications that do not describe a clinical trial will be administratively withdrawn.

An informational resource for preparing an application, the Human Subject Research Resource, is available on the CDMRP website.

Clinical Trial Start Date and Regulatory 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 six months of the award date.*** The regulatory application should be specific to 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***. It is strongly encouraged that applications not using military and/or Veteran populations for the proposed studies 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 FY26 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, or 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 clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE guidelines 2.0.

Use of DOW or VA Resources: Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the VA and other federal government agencies are highly encouraged. These relationships can leverage knowledge, datasets, 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, Veterans, their Families and the American Public. 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: The TERP has provided Appendix 4 as a reference, and it 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 limited examples provided 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.

3.3. Funding Instrument

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

3.4. Funding Details

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

Single PI Option:

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$4.5M**. 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.

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.

Partnering PI Option:

Cost Cap: The combined total costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **$4.5M**. 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.

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator (Single PI Option) and/or for one investigator from each partnering application (PPIO) to attend one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY26 TERP CTA.
- Research subject compensation and reimbursement for trial-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:

- Costs 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 DOW 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. Pre-Application Components

The PI or Initiating PI must submit the following pre-application components.

Upload documents as individual PDF files unless otherwise noted. Files must comply with the formatting guidelines listed in the GAI.

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

  The Preproposal Narrative should include the following:

  - **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 applicants will complete the study within the proposed period of performance.

- **Alignment:**
  - Describe how the proposed project addresses at least one FY26 TERP Program Goal and at least one FY26 TERP Topic Area.
- **Clinical Impact and Military Relevance:**
  - 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) that improve patient care and the quality of life for those impacted by or 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 *(only relevant for PPIO submissions)*:**
  - Briefly describe the interdisciplinary 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. Full Application Components

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

Partnering PI Option: The CDMRP requires separate full application package submissions for the Initiating PI and the Partnering PI, even if the PIs are located within the same organization. The application submission process for the Partnering PI uses an abbreviated full application package.

4.3.1. Full Application Components for the PI or 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)*:

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 in the GAI.

- **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using the outline below. It should be evident 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 and completed/ongoing studies relevant to the proposed clinical trial.
    - 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 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 trials; and describe how the proposed study differs.
    - State the relevance of the proposed research to at least one of the FY26 TERP Program Goals and at least one FY26 TERP Topic Area.

    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 how it compares with currently available interventions and/or standards of care.
  - **Objectives, Specific Aims and 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.

- **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 of what study participants will experience. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
  - Describe the type of study to be performed (e.g., treatment, prevention, diagnostic), including study phase or class (if applicable) and study model (e.g., single group, parallel, crossover).
  - 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 not involved 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, 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 objectives 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 in Attachment 2: Supporting Documentation. Describe the reliability and validity of the selected endpoints/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). Describe potential limitations to datasets and/or data collection instruments and the impact on research endpoints.

    If proposing clinical trials with Gulf War 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 and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical trial. 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 for a thorough evaluation of statistical calculations during review of the application.
  - Provide a statistical sample size estimate and the method by which it was derived, including power analysis calculations, to demonstrate that the 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.
  - Explain the statistical methods/model that will be used for data analysis.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, and how outliers will be defined and managed, if applicable.
  - Describe the randomization and blinding/masking procedures for the study, and any other measures to be taken to minimize the effects of subjective bias, if applicable.
  - 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".**

  There are no page limits for these components unless otherwise noted. Include only 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.

  - **References Cited:** List the references cited in the Project Narrative using a standard reference format (include URLs, if available).
  - **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; include 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 the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized 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. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI meets the eligibility criteria.

  As applicable, provide appropriate letters of commitment demonstrating the study team's access to the intervention(s) for the duration of the clinical trial.

  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 DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.

- **Sex as a Biological Variable Strategy (two-page limit is recommended):** If applicable, 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. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.

- **Research 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 the mechanism (e.g., direct sharing, repository, mixed mode) by which 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. Identify and provide the rationale for any data or resources that will not be shared (e.g., for intellectual property, feasibility, cost, or other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results 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.

  Do not submit a copy of the National Institutes of Health Data Management and Sharing Plan or duplicate the Data Management Plan, which will be requested only after a recommendation for funding is made.

Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the 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 page.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".**

Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

- **Background:** Present the ideas and rationale behind the proposed clinical trial.
- **Hypothesis/Objective(s):** State the hypothesis/research question to be addressed and the objective of the proposed clinical trial.
- **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) that improve patient care and the quality of life for those impacted by or likely to encounter toxic substances.
- **Relevance to the TERP:** Applications should articulate how the proposed research is relevant to at least one of the FY26 TERP Program Goals and addresses at least one of the FY26 TERP Topic Areas.
- **Military Relevance:** 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 should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

- 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 FY26 TERP Program Goals and at least one of the FY26 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.

  For guidance on preparing the SOW, refer to the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work. Include milestones for data or research resource(s) sharing.

  For applications submitted under the Partnering PI Option, each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the 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 the applicant is requesting funding for 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 DHA R&D Office of Research and Regulatory Compliance [ORRC] approvals, IND and IDE applications, as applicable). Refer to the GAI, 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, 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. 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 DOW 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 GAI, 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, enrollment 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 GAI contains additional considerations unique to DOW-sponsored research.

- **Risks/Benefits Assessment:**
  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Address special precautions to be taken by human subjects before, during and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention). If applicable, identify any potential risk to the study personnel.
  - **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 costs 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 about 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 regulatory application submission strategy.
    - 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. State 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 six 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 include an 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.

- 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: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as "Personnel.pdf".** The Study Personnel and Organization attachment should include the components listed below.
  - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and 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) 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. Investigators 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 or investors 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 next stage of clinical development/ implementation/dissemination. Include steps regarding Regulatory Agency approval as appropriate.
  - Describe strategies or frameworks required to advance evidence-based interventions into clinical practice. Discuss potential barriers to adoption across varied clinical environments.
  - 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. The discussion should include potential opportunities for securing funding through commercial sponsorship, venture capital, federal or nonfederal funding opportunities, or other relevant resources.
  - 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 Military Relevance (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 is 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 FY26 TERP Program Goals and at least one of the FY26 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 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.
- **Attachment 11: Partnership Statement (one-page limit) *(Attachment 11 is only applicable and required for applications submitted under the Partnering PI Option):* Upload as "Partnership.pdf".**
  - Describe the interdisciplinary partnership, including how the combined unique expertise of the Initiating and Partnering PI will better address the research question.
  - Describe how the combined effort will be synergistic and produce an outcome greater than what could be achieved by independent efforts.
  - Outline the contribution and time commitment of each PI and how each will have appropriately balanced intellectual input on the design, conduct, and analysis of the project.
  - Describe how the PIs will manage the collaboration and workflow to optimize research efforts.
- **Attachment 12: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.

- **Attachment 13: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOW 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 available on eBRAP.

(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.

Grants.gov	eBRAP.org

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

- **Biographical Sketch**
- **Current/Pending Support**

  Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for the Partnering PI, or vice versa, even if they are located within the same organization. Refer to Section 3.4, Funding Details, for detailed budget information.

iii. Project/Performance Site Location(s) Form

iv. Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov submissions only)*

4.3.2. Full Application Components for the 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 the Partnering PI.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov Submissions Only)*:

(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 12: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 13: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Additional Application Materials:

The following are additional application materials for application submission. Follow the instructions specific to the submission portal found within the GAI.

Grants.gov	eBRAP.org

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

- **Biographical Sketch**
- **Current/Pending Support**

  Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI should not include budget information for the Initiating PI, or vice versa, even if they are located within the same organization. Refer to Section 3.4, Funding Details, for detailed budget information.

iii. Project/Performance Site Location(s) Form

iv. Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov submissions only)*

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 HT942526TERPCTA from Grants.gov or eBRAP, depending on which submission portal will be used.

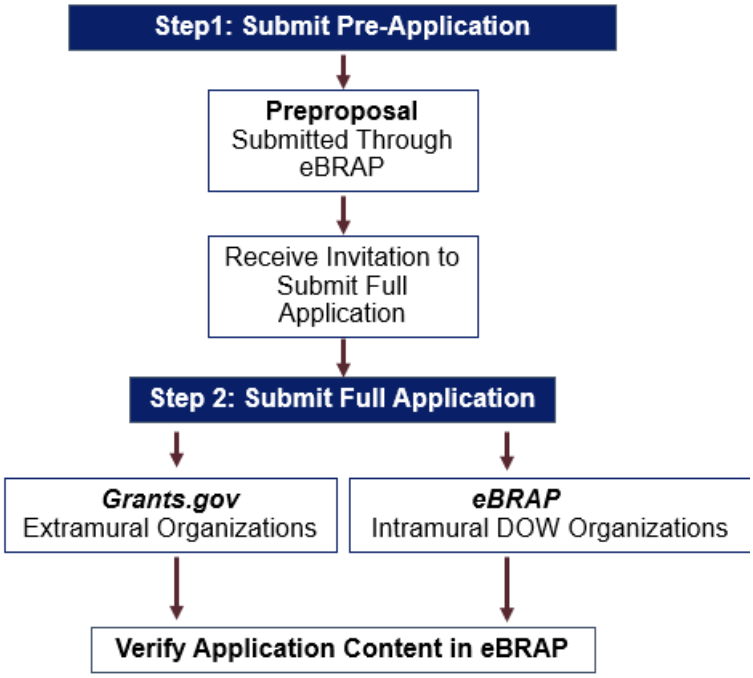
5.2. Unique Entity Identifier and System for Award Management

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.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

Application Submission Workflow



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI or initiating PI through eBRAP, including the submission of contact information for the Partnering PI if selecting the Partnering PI Option.

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. Contact the eBRAP Help Desk if any changes need to be made.

Partnering PI Option: After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI must follow the instructions provided in the email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

Partnering PIs 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:

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

When starting the pre-application, PIs should select a Mechanism Option appropriate to their pre-application:

Application Includes:	Select Mechanism Option:
Research by a **single PI**	Clinical Trial Award (CTA); select “no option”
Research by **two PIs**	Clinical Trial Award – Partnering PI Option (CTA – PPIO)

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

eBRAP Submissions: Only intramural DOW organizations may submit full applications through eBRAP.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. 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 DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

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 the 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 Directive 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.

Members of the FY26 TERP Programmatic Panel must 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 FY26 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 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 application clearly states the specific aims 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 FY26 TERP Program Goals and at least one of the FY26 TERP Topic Areas.
  - Whether the proposed project adheres to the intent of the FY26 TERP and is compliant with the program's Additional Guidance.

- **Clinical Impact and Military Relevance**
  - To what degree the proposed research project will have both short- and long-term impacts, and how 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 impacted by or 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 *(applicable only to PPIO submissions)***
  - How well the proposed study describes the interdisciplinary 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 evaluated individually according to the following **scored criteria**, which are of equal importance:

- **Clinical Impact and Military Relevance**
  - To what extent a successful outcome(s) of the proposed clinical trial will advance at least one of the FY26 TERP Program Goals and at least one of the FY26 TERP Topic Areas.
  - How well the application describes the short-term impacts and benefits for individuals, including the anticipated outcomes or products (intellectual knowledge or tangible materiel) that will be directly attributed to the results of the proposed clinical trial.
  - 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 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 by a 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.

- How well the application addresses limitations of datasets and/or data collection instruments and the impact on research endpoints.
- For studies involving GW Veterans, 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.
- 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.
- To what degree the planned route and schedule of study intervention(s), evaluations(s), and follow-up procedures are 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 and 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.
  - 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 six 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 Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (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.
- How well the strategies or frameworks required to advance evidence-based interventions into clinical practice, including potential barriers to adoption across varied clinical environments, are described.
- 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.
  - 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.
- **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.
- **Personnel and Study Management**
  - 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.

Applicable for applications submitted to the Partnering PI Option:

- To what degree the interdisciplinary partnership and combined unique expertise of the Initiating and Partnering PI will better address the research question and produce an outcome greater than that achieved through separate independent efforts.
- How well the application reflects that each PI will have appropriately balanced intellectual input into the design, conduct, and analysis of the project.

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**:

- **Research Sharing Plan**
  - To what extent the plan for sharing project data and research resources is appropriate and reasonable, and includes dissemination to affected communities, study participants, and/or the scientific community. If applicable, whether specific repository(ies) are named where data and research resources arising from the project will be stored.
- **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 peer reviewers
- Relevance to the priorities of the FY26 TERP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition and balance
  - Relative impact and military relevance

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, 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 subject to review and approval by a designated official. ***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 the SAM.

An applicant organization may review the 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-33 and all associated laws, all fundamental research funded by the DOW 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 compliant 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. After all awards are made, the CDMRP includes individual award information in a searchable database.

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 DHACA 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).***

Intragovernmental 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 DOW 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 DOW 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.

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.

The GAI contain information regarding administrative requirements and national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the DHACA Terms and Conditions for further information.

If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards 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 clinical trials to register and submit study results on ClinicalTrials.gov.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB) or Ethics Committee (EC) review.

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 progress 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.

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

PHS Inclusion Enrollment Reporting *(Required for research proposing clinical research and/or clinical trials)*: Enrollment reporting on the basis of sex, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period

and that were connected with their 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.

8.3. Additional Requirements

Unless otherwise restricted, changes in the PI 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.

9. Other Information

9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01Td.

9.2. Administrative Actions

After receipt of 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.
- The Project Narrative is missing.
- The Budget is missing.
- Study Population Recruitment and Safety Plan (Attachment 6) is missing.
- Regulatory Strategy (Attachment 7) is missing.
- Study Personnel and Organization (Attachment 8) is missing.
- Post-Award Transition Plan (Attachment 9) is missing.
- Partnership Statement (Attachment 11) is missing for CTA – PPIO applications.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing 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 FY26 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.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, 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.

- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.
- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b) 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.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The 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) applications by the deadline (for CTA – PPIO applications).
- The PI, or the Initiating and/or Partnering PI (for CTA – PPIO applications), does not meet the eligibility criteria.
- The applicant is named as a PI on more than one application to the TERP.
- The invited application proposes a different research project than that described in the pre-application.
- The same research project is submitted 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 DHACA Grants Officer for a determination of the final disposition of the application.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/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"	☐	
Study Personnel and Organization – Attachment 8, upload as "Personnel.pdf"	☐	
Post-Award Transition Plan – Attachment 9, upload as "Transition.pdf"	☐	
Clinical Impact and Military Relevance – Attachment 10, upload as "Impact.pdf"	☐	
Partnership Statement ***(if applicable)*** **– Attachment 11, upload as "Partnership.pdf"**	☐	
Representations ***(Grants.gov submissions only)*** **– Attachment 12, upload as "RequiredReps.pdf"**	☐	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 13, upload as "IGBudget.pdf"**	☐	☐
Additional Application Materials		
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	☐	☐
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	☐	☐
Research & Related Budget	☐	☐
Project/Performance Site Location(s)	☐	☐
Research & Related Subaward Budget Attachment(s) ***(if applicable)***	☐	☐

Appendix 2. Acronym List

ARRIVE	Animal Research: Reporting of In Vivo Experiments
CDC	U.S. Centers for Disease Control and Prevention
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
CTA	Clinical Trial Award
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GAI	General Application Instructions
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GWI	Gulf War Illness
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
ORRC	Office of Research and Regulatory Compliance
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator

PPIO	Partnering Principal Investigator Option
R&D	Research and Development
ROC	Roles of Care; Role of Care
RPPR	Research Performance Progress Report
SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
SOW	Statement of Work
TERP	Toxic Exposures Research Program
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs

Appendix 3. TERP Definitions

The TERP uses the following definitions:

- **Fourth Generation Agents:** "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 from 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 DOW CDMRP GWIRP assembled multiple resources that applicants may find helpful if proposing studies on GWI.
    - **Common Data Elements for GWI Clinical Research:** Through a collaboration among the NIH, CDC, VA, former DOW 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:** 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:** "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:** "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 4. Resources for Data and/or Previously Collected Biospecimens

Boston Biorepository, Recruitment and Integrated Network for GWI (BBRAIN)
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)