
**Program Announcement for the Defense Health Agency**

# Traumatic Brain Injury and Psychological Health Research Program

# Clinical Trial Award

Funding Opportunity Number: HT942526TBIPHRPCTA

Pre-Application Due: July 13, 2026

Application Due: October 15, 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) Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP) Clinical Trial Award (CTA) intends to support clinical trials with the potential to have a significant impact on psychological health conditions and/or traumatic brain injury (TBI) through clinical applications, including health care products, technologies and/or practice guidelines.

**Distinctive Features:** Funding from this award mechanism must support a clinical trial.

- Clinical trials may be designed to evaluate a wide range of interventions, including new drugs, biologics, medical devices, diagnostics, therapies and behavioral health strategies.
- Preliminary data are required.
- The inclusion of community-based participatory research (CBPR) approaches is required.
- The CTA offers funding for two Research Levels. The applicant is responsible for selecting the Research Level based on the scope of the research.
    - **Research Level 1:** Supports proof-of-principle pilot studies, as well as phase 1 and phase 2 clinical trials.
    - **Research Level 2:** Supports larger-scale and advanced clinical trials that evaluate effectiveness in relevant patient populations.
- **Early-Career Investigator Partnering Option (*available for both Research Levels*):** This option accommodates two Principal Investigators (PIs), one of which is an Early-Career Investigator. If recommended for funding, each PI will receive a separate award.

**Funding Details:** The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $18.6M to fund approximately three Research Level 1 and three Research Level 2 applications with total cost caps of $2.1M (Research Level 1) and $4.1M (Research Level 2). 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), July 13, 2026
- **Invitation to Submit an Application:** August 27, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, October 15, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, October 20, 2026
- **Peer Review:** December 2026
- **Programmatic Review:** March 2027

**Announcement Type:** Initial

**Funding Opportunity Number:** HT942526TBIPHRP

**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 affiliated with an eligible organization are eligible to be named as PI, Initiating PI or Partnering PI on the application, regardless of ethnicity, nationality or citizenship status. ***Individuals in mentored positions (e.g., postdoctoral fellows, clinical fellows) are not considered independent investigators.***

**Early-Career Investigator Partnering Option (ECIPO):**

For applications that select the Early-Career Investigator Partnering Option, both PIs must be independent investigators, and the Early-Career Investigator must be within 10 years after completion of their terminal degree by the time of the application submission deadline (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is included. Lapses in research time or appointments as denoted in the biographical sketch should be explained in the application. For Early-Career Investigator Partnering Option applications, at least one of the named PIs must be an Early-Career Investigator.

**Application limit:** The same independent investigator may not be named as a PI, Initiating PI, or Partnering PI on more than four CTA applications.

## 2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

## 2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions (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 Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP). 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 TBIPHRP in FY07 in response to the traumatic brain injuries (TBIs) sustained and psychological health issues experienced by our deployed forces in Iraq and Afghanistan. The TBIPHRP complements ongoing DOW efforts toward promoting a better standard of care for TBI and psychological health in the areas of prevention, detection, diagnosis, treatment and rehabilitation. Appropriations for the TBIPHRP from FY07 through FY24 totaled $2.6 billion. The FY26 appropriation is $40.5 million (M).

The vision of the TBIPHRP is to optimize the prevention, assessment and treatment of psychological health conditions and/or TBIs. The program seeks to fund research that understands, prevents and treats psychological health conditions and/or traumatic brain injuries that accelerates solutions to improve the health, well-being and health care of Service Members, DOW beneficiaries, Veterans and the American Public.

## 3.1. Award History

The TBIPHRP first offered the Clinical Trial Award mechanism in FY21. Since then, 289 Clinical Trial Award applications/proposals were received, and 83 were recommended for funding.

## 3.2. Intent of the Clinical Trial Award

The TBIPHRP Clinical Trial Award mechanism supports the rapid execution of clinical trials with the potential to have a significant impact on the treatment or management of psychological health conditions and/or traumatic brain injuries.

Clinical trials may be designed to evaluate a wide range of interventions, including new drugs, biologics, medical devices, diagnostics, therapies and behavioral health strategies. Proposed research may range from proof-of-concept trials (i.e., pilot, first-in-human, phase 0) that establish feasibility to larger scale and advanced trials that evaluate effectiveness in relevant patient populations.

### 3.2.1. Focus Areas for the CTA

To meet the intent of the funding opportunity, applications ***must address at least one sub-area*** **(*e.g., 1a, 1b, 2a, 2b)*** within one of the two FY26 TBIPHRP CTA focus areas listed below. Bulleted items are provided in Appendix 3 to indicate additional context regarding programmatic intent but are not required to be specifically addressed by applications. Selection of the appropriate FY26 TBIPHRP CTA focus area is the responsibility of the applicant.

1. **Prevent and Assess:** Research will address the prevention, screening, diagnosis or prognosis of psychological health conditions and/or TBI.
    a. Identification and validation of biomarkers or other objective methods for assessment, diagnosis, prognosis or real-time monitoring of psychological health conditions and/or TBI, including subclinical presentations, and associated sequelae of these conditions.

- Development of decision-making frameworks or tools that incorporate objective assessments and may consider long-term outcomes to inform return-to-activity/duty decisions are within scope.

b. Development and evaluation of approaches or tools to prevent or reduce risk of psychological health conditions and/or TBI.

c. Development and evaluation of crosscutting prevention approaches to address multiple adverse outcomes such as suicide, interpersonal violence including intimate partner and family violence, sexual assault, psychological health issues and/or TBI.

- Crosscutting prevention approaches refer to strategies that enhance protective factors and reduce risk factors at multiple socio-ecological levels (e.g., individual, relationship and community).

d. Development and evaluation of solutions to support military and Family readiness and increase psychological resilience in individuals to the potential negative impacts of specific military and life stressors.

- Military readiness refers to the ability of military forces to fight and meet the demands of national military strategy; Family readiness is the state of preparedness to effectively navigate the challenges of daily living experienced in the unique context of military service.

2. **Treat:** Research will address novel and repurposed interventions to improve the outcomes of psychological health conditions and/or TBI. Efforts that address treatment, rehabilitation and health services research are within scope.

a. Interventions that promote sustained functional recovery, including interventions administered acutely, during the post-acute phase or chronic phase of injury.

b. Development of postvention strategies to support individuals in workplace or community environments following a sexual assault, suicide event or other trauma.

- Postvention refers to response activities that should be undertaken in the immediate aftermath of a suicide that has impacted the unit. Postvention has two purposes: to help suicide attempt survivors cope with their grief, and to prevent additional suicide.

c. Health services research to improve the adoption of evidence-based practices, access to care, or reduce barriers to care. Individual and systemic factors that influence access to or barriers to care as well as other factors that influence treatment engagement, follow-up care and improvement of long-term outcomes are applicable.

### 3.2.2. Key Elements for the CTA

***Proposed research can be aligned with TBI, psychological health, or in combination.***

**Preliminary Data:** Inclusion of preliminary data relevant to the proposed clinical trial is required.

**Study Population**: The proposed research solution(s) should be representative of the characteristics and priorities of the population(s) intended to benefit from the research.

**Intervention Availability:** The application should demonstrate the documented availability of and access to the drug/compound, device and/or other materials needed, as appropriate, for the proposed duration of the study.

**Precision Medicine Approaches:** When appropriate, the TBIPHRP encourages the use of precision medicine approaches. These tailored treatments deliver the right treatment at the right time while considering an individual's unique characteristics.

**Personnel and Environment:** The application should demonstrate the study team's expertise and experience in all aspects of conducting clinical trials, including appropriate statistical analysis and knowledge of Regulatory Agency processes (if applicable). The application should include a study coordinator(s) who will guide the clinical protocol through the local Institutional Review Board (IRB) of record and other federal agency regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual. The application should show strong institutional support and, if applicable, a commitment to serve as the regulatory sponsor, ensuring all sponsor responsibilities described in the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312), Subpart D, for U.S. Food and Drug Administration (FDA)-regulated studies.

**Research Levels:** The TBIPHRP CTA offers funding for two Research Levels (refer to Section 3.4, Funding Details). Applicants may choose only one Research Level per application. The applicant is responsible for selecting the Research Level that aligns with the scope of the proposed research. The Research Level selected should be based on the research scope and not on the amount of the budget. The following are generalized descriptions of the scope of the research appropriate for each Research Level.

- **Research Level 1:** Supports proof-of-principle pilot studies, as well as phase 1 and phase 2 clinical trials.
- **Research Level 2:** Supports larger-scale and advanced clinical trials that evaluate effectiveness in relevant patient populations.

**Early-Career Investigator Partnering Option (available for both research levels):** Both Research Levels include an option for more than one PI. 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. The intent is not to create a mentor-mentee arrangement. Both PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory and administrative requirements. For individual submission requirements for the Initiating and Partnering PI(s), refer to Section 5.3, Submission Instructions.

### 3.2.3. Other Important Considerations for the CTA

**Clinical Trial Start Date:** The proposed clinical trial is expected to begin no later than 12 months after the award date or 18 months after the award date for 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.

**Hypothesis-Driven Research:** Applications consisting solely or primarily of planning, engineering, manufacturing, or formulation activities, without a core, scientific hypothesis and testing, may be administratively withdrawn.

**Research requiring an exception from informed consent (EFIC) is prohibited**.

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

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

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 by the Clinical Trial Award application submission deadline*.** The regulatory application should be specific to the product and indication to be tested in the proposed clinical trial.

**Regulatory Strategy (if applicable):** All interventions, even if they are not FDA-regulated (or international equivalent), are within scope but the regulatory status must be documented in Attachment 7, Regulatory Strategy.

**Community-Based Participatory Research:** Applicants should propose research that directly addresses the psychological health conditions and TBI needs of people with lived experience, their families and care providers. These partnerships are key to maximizing the translational potential and impact of research. CBPR approaches can be documented in Attachment 12, CBPR Documentation. Additional information can be found in Appendix 4.

**Data Sharing Requirements for Traumatic Brain Injury or Psychological Health Human Subjects Research:** The CDMRP intends that information, data and research resources generated under this funding opportunity will be made available to the research community and the public at large. The information below outlines the mandatory data and sharing requirements for all prospective human-subjects research:

- Informed consent: Consent forms must allow for the submission of de-identified data to a repository. It is also strongly encouraged to include language for optional passive follow-up via electronic health records (EHR).
- Common Data Elements (CDEs): Use of CDEs relevant to the field of study (e.g., National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs, PhenX collections) is mandatory. Justification is required if CDEs are not used.
- Secondary Outcomes: Applicants are strongly encouraged to include secondary outcomes to address potential crosscutting impacts
- For studies prospectively enrolling 50 or more subjects, applications must share data in an appropriate repository based on the application's research area. Recommended repositories are below:
    - National Institute of Mental Health Data Archive (NDA): The NDA houses, harmonizes and shares all human-subjects data collected as part of NIMH-funded projects, with the goal of accelerating progress in mental health research. Applicants should use the NDA cost estimation tool to budget for manpower and associated costs.
    - Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System: FITBIR is a central repository to promote collaboration, accelerate research and advance knowledge on the characterization, prevention, diagnosis and treatment of TBI. Applicants should use the FITBIR cost estimation tool to budget for manpower and associated costs.
    - Additional National Institutes of Health (NIH)-supported Data Repositories can be found at https://www.nlm.nih.gov/NIHbmic/domain_specific_repositories.html

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 2.0 guidelines.

Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the U.S. Department of Veterans Affairs (VA) and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, 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.

PIs are encouraged to integrate and/or align their research projects with DOW and/or VA research laboratories and programs. Collaboration with the DOW and/or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOW and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 10 of the GAI.

**Classified research is prohibited**. This includes classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns may result in application withdrawal. This includes, but is not limited to, research involving directed energy (e.g., photonic, radio frequency, acoustic energy, other non-kinetic sources), anomalous health incidents, Havana syndrome and associated neurological syndromes/injuries. Refer to the GAI, Appendix 7, Section C.

## 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.

### 3.4.1. Application Submission With a Single PI

- ***For Research Level 1***
  - **Cost Cap:** The application's/proposal's total costs budgeted for the entire period of performance should not exceed **$2.1M**.
- ***For Research Level 2***
  - **Cost Cap:** The application's/proposal's total costs budgeted for the entire period of performance should not exceed **$4.1M**.

### 3.4.2. Application Submission With the Early-Career Investigator Partnering Option

- ***For Research Level 1***
  - **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 **$2.1M**.
- ***For Research Level 2***
  - **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 **$4.1M**.

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

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

### 3.4.3. For Both Options Within This Award Mechanism

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.

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

Must be requested for:

- In Years 3 and 4, travel costs for the **PI** or **Initiating PI and Partnering PI** to present project information or disseminate project results at a DOW-sponsored meeting (e.g., Military Health System Research Symposium). For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area.

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Starting in Year 2, travel costs for the **PI** or **Initiating PI and Partnering PI** to present project information or disseminate project results at one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY26 TBIPHRP 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).
- Costs associated with data and research resource sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community). If recommended for funding, the government reserves the right to reduce the data/resource sharing budget request during negotiations in order to maximize funding available for research. The TBIPHRP will not provide future TBIPHRP funds to preserve or share data/resources indefinitely.

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.
- Tuition.

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

  The Preproposal Narrative should include the following:

  - **Focus Area:** Describe how the proposed project is relevant to the selected sub-area(s) within one of the two FY26 TBIPHRP CTA Focus Areas.
  - **Background and Rationale:** Describe the scientific rationale on which the proposed work is based; **include relevant preliminary data** and literature citations. Identify the phase of the clinical trial proposed.
  - **Specific Aims and Study Design:** Concisely state the hypothesis and specific aims. Provide a brief overview of the study design. Briefly describe the intended subject population(s). As applicable, identify the availability of and accessibility to the intervention. As applicable, provide the regulatory status (including device classification) and identify the regulatory sponsor. Indicate how the study design is informed by the CBPR approach. Identify and justify the requested Research Level.
  - **Research Team:** Briefly state the qualifications and expected contributions of the PI(s), CBPR approach and key personnel to perform the clinical trial. Note any DOW or VA collaborations. Explain how the project incorporates CBPR.
  - **Impact and Relevance to Military Health:** Describe how the clinical trial will improve the prevention, assessment and treatment of psychological health conditions and/or traumatic brain injuries. Describe how the research is relevant to the health care needs of Service Members.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application/pre-proposal ***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).
    - **Other Pre-Applications (two-page limit)**: If applicable, provide a list of all FY26 CTA pre-applications where the PI is also named as a PI, Initiating PI, Partnering PI, or collaborator. Each entry must include the CDMRP log number, the PI's role, the project title, the specific aims and a brief explanation of how each pre-application's research questions are distinct.
    - **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. Biographical sketches, or equivalent document, should also be included for lived-experience consultants (LECs) or community-based partners to demonstrate background and experience related to their role in the proposed research project. Letters of support are not appropriate and will be removed. (For administrative purposes, please use the label “Consumer” when assigning the community partners’ roles in eBRAP).

## 4.3. Full Application Components

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

**Early-Career Investigator Partnering Option:** The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. 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.

- **Background:** Describe in detail the scientific rationale for the study. Provide a review and analysis of relevant literature, unpublished data, preliminary studies/data and/or preclinical data relevant to the proposed clinical trial.
  - Describe the preliminary studies and/or preclinical data that support the proposed clinical trial.
  - Summarize key preclinical pharmacological findings, dosage studies and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.
  - Provide a summary of other relevant ongoing, planned or completed clinical trials, and describe how the proposed study differs.
  - Describe any CBPR/stakeholder engagement that was performed and how it helped to formulate the hypothesis/objective and research strategy. ***Full details of the CBPR approach should be provided in Attachment 12.***

  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 support/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.
- **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. The aims should align with the associated tasks described in the Statement of Work (SOW) (Attachment 5).
- **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. Describe how the proposed research aligns with at least one of the sub-area(s) within one of the three FY26 TBIPHRP CTA Focus Areas and is appropriate for the requested Research Level. 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. 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).
- 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 9: Study Population Recruitment and Safety Plan.
- 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. ***Note that CDMRP will not serve as the government sponsor or signatory on any access applications or agreements for DOW or VA patient populations, resources or databases***. 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.

– **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.

- Include a complete power analysis to demonstrate that the proposed clinical trial's anticipated sample size is appropriate to meet the objectives of the study. Describe all clinical and statistical justifications and assumptions that support the sample size calculations. Explain any anticipated subgroup analyses and demonstrate that such analyses will be appropriately powered.
- Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. Refer to

the CDMRP Directive on Sex as a Biological Variable in Research for additional information.

- For phase 3 clinical trials, describe plans for the valid and sufficiently powered analysis of group differences on the basis on sex, race and/or ethnicity as appropriate for the scientific goals of the study. Refer to the CDMRP Directive on the Inclusion of Women and Minorities as Subjects in Clinical Research for additional information on the requirements for phase 3 studies.

– **Pitfalls and Mitigation Strategy:** Describe potential challenges and discuss alternative methods/approaches that may be employed to overcome them.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".**

***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 or may result in administrative withdrawal of the application.***

– **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(s) meet 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 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. ***Note that CDMRP will not serve as the government sponsor or signatory on any access applications or agreements for DOW or VA patient populations, resources, or databases.***

- **Sex as a Biological Variable Strategy (two-page limit is recommended):** 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. 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 NIH 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:** 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 under development.
- **Quad Chart:** Provide a Quad Chart for the proposed project. The format for the Quad Chart is available on the eBRAP "Funding Opportunities & Forms" web page.

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

  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 objective of the proposed clinical trial and the hypothesis/research question to be addressed.
  - **Specific Aims:** State the specific aims of the study.

- **Study Design:** Briefly describe the study design, including identifying the clinical trial phase, intervention, controls and primary outcome measure(s).
- **Clinical Impact:** Briefly describe the potential near-term and long-term impact of the results of the proposed research on psychological health conditions and/or TBI research, patient care and the sub-area(s) within one of the FY26 TBIPHRP CTA Focus Areas to be addressed. Describe how the research aligns with the intent of the FY26 TBIPHRP CTA.
- **Relevance to Military Health:** Describe how the study is relevant to Service Members, Veterans and Families impacted by psychological health conditions and/or TBI.

○ **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.***

- Summarize the objectives and rationale for the proposed clinical trial and the alignment to the selected FY26 TBIPHRP CTA Focus Areas sub-area(s).
- Describe the CBPR approach and implementation in the study.
- Describe the intervention(s).
- Identify the population the research will help and how it will help them.
- Describe the expected clinical applications and potential risks of the anticipated outcomes.
- Describe the ultimate applicability and impact of the proposed study and the anticipated outcomes to advancing research, patient care and/or quality of life.
- Describe the potential benefit of the proposed study and the anticipated outcomes to Service Members, Veterans and/or their Families.

○ **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 either the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work or Example: Assembling a Generic Statement of Work, whichever is most appropriate for the proposed effort..

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

- If applicable, include cross-mapping of data elements to psychological health conditions and/or TBI CDEs.
- Include milestones associated with data or research resource(s) sharing and executing the CBPR approach.

**Early-Career Investigator Partnering 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.

- **Attachment 6: Impact Statement (two-page limit): Upload as "Impact.pdf".** The Impact Statement is considered by reviewers on the peer review and programmatic review panels and therefore should be written in a manner that will be ***readily understood by the general public, especially those without a background in science or medicine.***
  - Summarize the potential benefit(s) of the intervention and/or research outcome of the proposed clinical trial as it relates to the FY26 TBIPHRP CTA Focus Areas.
  - Detail the anticipated research outcome(s) that will be directly attributed to the results of the proposed clinical trial, and describe the anticipated benefits of these outcomes for individuals and the research field. Describe any relevant controversies, treatment issues or health disparities that will be addressed by the proposed clinical trial.
  - Explain the long-range vision for how implementation/dissemination of the intervention and/or research outcome(s) will improve patient care and/or quality of life for the target population. Describe how the intervention represents an improvement over currently available interventions and/or standards of care.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
  - Describe any potential challenges that might limit the impact of the proposed clinical trial, including barriers to implementation or acceptance by users.
- **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***

***prior to the FY26 TBIPHRP Clinical Trial Award application submission deadline.*** 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. If available, 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: 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.
  - 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 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 9: Study Population Recruitment and Safety Plan (no page limit): Upload as "StudyPopPlan.pdf".** Include the components listed below.
  - **Enrollment Distribution:** Provide anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report. The enrollment table(s) should be appropriate to the objectives of the study.
  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. If limiting inclusion by age, race, ethnicity or sex, provide strong rationale based on justification from scientific literature, preliminary data or other relevant considerations. List and describe any evaluations (e.g., laboratory procedures, history or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Describe how the study population represents the population anticipated to benefit from the intervention.
  - **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 research/trials that compete for the same population.
  - **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 General Application Instructions 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 the 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 10: Partnership Statement (two-page limit): Upload as "Partnership.pdf".** ***(Attachment 10 is required for applications submitted under the Early-Career Investigator Partnering Option.)***.
  - Provide a statement confirming that the Early-Career Investigator meets the eligibility requirements. ***Individuals in mentored positions (e.g. postdoctoral fellows, clinical fellows) are not considered independent investigators***.
    - Provide the completion dates of the terminal degree and last postdoctoral/ fellowship position.
    - Provide an explanation of any lapses in research time or appointments as denoted in the biographical sketch.
  - Describe how the partnership and combined experience/expertise of both PIs are critical to the research strategy and completion of the SOW.
  - Explain how the partnership will better address the research question and why the work should be done together rather than through separate individual efforts.
  - Explain how both PIs will contribute equally to the project's design, provide balanced intellectual input and dedicate appropriate levels of effort to its execution.
- **Attachment 11: 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 of the study team in enough detail to determine whether the team includes relevant subject matter expertise to accomplish the proposed work. Include the roles of individuals named in the organizational chart along with any external consultants or advisors who will provide critical guidance and input to the study team (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate). Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed clinical trial.
- **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 12: CBPR Documentation (no page limit):** Complete CBPR Documentation requires the CBPR Letters of Support AND CBPR Statement. **Start each component on a new page. Combine and upload as "CBPR.pdf".**
  - **CBPR Letters of Support (two-page limit per letter is recommended):** Provide a letter signed by each LEC/consumer or community-based partner(s) confirming their role and commitment to participate on the research team. The letter should include the qualifications and background of the LEC(s) or community-based partner(s) and their relevance to the proposed research project.
  - **CBPR Statement (three-page limit is recommended):** Description of the CBPR approach that will be used (e.g., LEC/consumer, partner organization, Community Advisory Board (CAB), co-researcher model) and at what points it will contribute to the research project. Description of the CBPR input that will be captured and how this input will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis and dissemination of the research. Include a description of how CBPR effectiveness will be assessed. Description of training that will be provided to both scientific researchers and community members on CBPR approaches, decision-making and equitable participation. Description of resource allocation, decision-making processes and authorship between scientific researchers and community partners (whether individuals or organizations). Description of dissemination activities that will share research findings with the stakeholder communities.
- **Attachment 13: Relevance to Military Health Statement (two-page limit): Upload as "Military.pdf".** Describe how the proposed effort is responsive to the health care needs of Service Members. ***Attachment 13 will be available for programmatic review only***.

- If applicable, clearly articulate how the proposed research is likely to enhance readiness and recovery on the battlefield, during training, or in resource-limited environments. ***Note that per DOW Instruction 6200.02, the DOW preferentially uses medical countermeasures that are approved by the FDA.*** Applicants should address this requirement if appropriate.
- If applicable, describe how the study team composition can provide military-relevant subject matter expertise to the proposed research.
- If applicable, describe how the proposed research project complements DOW and/or VA areas of research interest and/or patient care for psychological health conditions and/or TBI.
- Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.

- **Attachment 14: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.
- **Attachment 15: 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 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)*

### 4.3.2. 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 14: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 15: 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(s) 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 HT942526TBIPHRPCTA from Grants.gov or eBRAP, depending on which submission portal will be used.

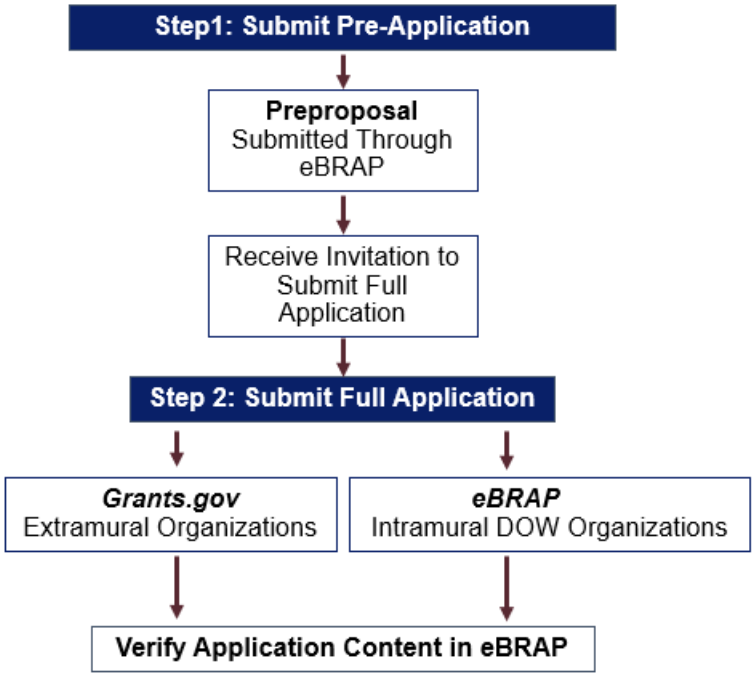
## 5.2. Unique Entity Identifier and System for Award Management

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 Early-Career Investigator Partnering 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.

**Early-Career Investigator Partnering 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 link in the notification email to associate the partnering pre-application with their eBRAP account and confirm their organization and Business Official information.*** 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 PIs 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: |
|---|---|
| Single PI (Research Level 1) | CTA-RL1 |
| Early-Career Investigator Partnering PI (Research Level 1) | CTA-RL1-ECIPO |
| Single PI (Research Level 2) | CTA-RL2 |
| Early-Career Investigator Partnering PI (Research Level 2) | CTA-RL2-ECIPO |

### 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 TBIPHRP 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 TBIPHRP 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 TBIPHRP, pre-applications will be screened based on the following criteria:

- **Focus Area:** The degree to which the proposed clinical trial is relevant to the selected sub-area(s) within one of the two FY26 TBIPHRP CTA Focus Areas.
- **Background and Rationale:** How well the ideas and reasoning on which the proposed work is based are supported by relevant preliminary data and literature citations.
- **Specific Aims and Study Design:** To what extent the study design will address the specific aims. How well the availability of and access to the resources and subject population is described and feasible. To what extent the requested Research Level is appropriate. To what extent the study design is informed by the CBPR approach.
- **Research Team:** How the qualifications and expected contributions of the PI(s), CBPR approach and other key personnel are appropriate to successfully complete the clinical trial.
- **Impact and Relevance to Military Health:** The degree to which the proposed clinical trial will improve the prevention, assessment and treatment of psychological health conditions and/or traumatic brain injuries. How well the research is relevant to the health care needs of Service Members.

### 6.2.2. Peer Review Criteria

To determine technical merit, all applications will be evaluated individually according to the following **scored criteria**, of which **Research Strategy and Feasibility** and **Clinical Impact** are equally of most importance and the remaining criteria listed are of equal importance to each other**:**

- **Research Strategy and Feasibility**
  - How well the scientific rationale for the proposed clinical trial is supported by the review and analysis of the available literature and completed/ongoing studies.
  - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
  - 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 studies are designed to achieve reproducible and rigorous results, including the endpoints/outcomes to be measured.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study 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.
  - How well potential challenges and alternative strategies are discussed.
  - Whether there is evidence indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
  - If applicable, whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
- **Clinical Impact**
  - To what degree the intervention addresses current clinical need(s), improves upon available interventions and/or standards of care, or addresses controversies, treatment issues or health disparities within the field.
  - How impactful the anticipated outcomes of the proposed clinical trial would be to the target population with regard to the selected FY26 TBIPHRP CTA Focus Area(s).
  - If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- **Recruitment, Accrual and Retention**
  - To what degree the plan for accessing, recruiting, enrolling and retaining study participants is reasonable to meet the needs of the proposed clinical trial.
  - 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.

- **Regulatory Strategy and Post-Award Transition Plan**
  - 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) has been submitted to the Regulatory Agency, as appropriate.
  - 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.
  - To what degree the next logical steps to be taken upon successful completion of the proposed clinical trial are realistic and appropriate to bring the research outcome(s) to the next stage of clinical development/implementation/dissemination.
  - 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 outcome(s) 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 planned for.
- **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 of seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
  - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.
  - If applicable, to what degree barriers to clinical trial participation have been considered and/or addressed.

- **Personnel and Communication**
  - To what degree the composition of the study team, including any external consultants or advisors (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate), is 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.
- **Partnership (*for Early-Career Investigator Partnering Option applications*)**
  - Whether the Early-Career Investigator meets the eligibility requirements.
  - To what degree the partnership and combined experience/expertise of both PIs are critical to the research strategy and completion of the SOW.
  - How well the application reflects that both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project.
  - To what degree the partnership will better address the research question together rather than through separate, individual efforts.
- **Community-Based Participatory Research**
  - To what extent CBPR/stakeholder engagement was performed, and to what degree it helped formulate the project's hypothesis/objective and research strategy.
  - To what extent the CBPR Letter(s) of Commitment describe the role and commitment of the lived-experience or community-based partners on the research team.
  - How well the CBPR approach that will be used (e.g., LEC, partner organization, CAB, co-researcher model) is described and at what points it will contribute to the overall program or research project.
  - To what extent the CBPR input will be captured and meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis and dissemination of the research.
  - To what extent training will be provided to both scientific researchers and community members on CBPR approaches, decision making and equitable participation.
  - To what degree dissemination activities will share research findings with the stakeholder communities.
- **Research Sharing Plan**
  - To what extent the plan for sharing of 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.

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**:

- **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 TBIPHRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact
  - Relevance to military health

### 6.3. Application Review and Selection Process

#### 6.3.1. Pre-Application

Following the pre-application screening, Initiating PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section 1, Basic Information about the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted

#### 6.3.2. Full Application

All applications are evaluated by scientists, clinicians and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are 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 TBIPHRP 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), IRB or Ethics Committee (EC) review.

The TBIPHRP requires that all TBI-, psychological health-related clinical research with at least 50 subjects funded by this program be shared through the jointly supported DOW-NIH Federal Interagency Traumatic Brain Injury Research or National Institute of Mental Health Data Archive repositories, respectively. Recipients will be required to upload study data annually and in accordance with the FITBIR or NDA data submission policies. There is no fee to use FITBIR or NDA, and detailed guidance and policies, including a cost estimator tool for budgeting considerations, can be found on their websites.

## 8.2. Reporting

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

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

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

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

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

**In-Progress Review meeting:** The PI(s) will be required to present an update on progress toward accomplishing the goals of the award at an In-Progress Review meeting (IPR) to be held virtually during Years 2 through 4 of the period of performance. The PI may include up to three additional members of the research team, including their CBRP partner(s), as participants in the meeting. The IPR may be attended by members of the TBIPHRP Programmatic Panel, CDMRP staff, the DHACA Grants Officer and other stakeholders.

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 supporting the Initiating PI or Partnering PI is discouraged and will be evaluated 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 pre-application or full applications, the following administrative actions may occur.

### 9.2.1. Rejection

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

- Preproposal Narrative is missing.
- Preproposal Narrative exceeds page limit.

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

- The Project Narrative is missing.
- The Budget is missing.
- Submission of an application for which a letter of invitation was not issued.
- Impact Statement (Attachment 6) is missing.
- The Regulatory Strategy (Attachment 7) is missing.
- Post-Award Transition Plan (Attachment 8) is missing.
- The Study Population Recruitment and Safety Plan (Attachment 9) is missing.
- The Study Personnel and Organization (Attachment 11) is missing.
- CBPR Documentation (Attachment 12) is missing.
- Relevance to Military Health Statement (Attachment 13), is missing

***For Early-Career Investigator Partnering Option applications:***

- Partnership Statement (Attachment 10) is missing.

### 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 TBIPHRP 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.
- The same research project is submitted to different funding opportunities within the same program and fiscal year.
- The same independent investigator is named as a PI, Initiating PI or Partnering PI on more than four CTA applications. Only the first four applications received will be accepted; additional applications will be administratively withdrawn.
- The invited application proposes a different research project than that described in the pre-application.
- Application consists solely or primarily of planning, engineering, manufacturing, or formulation activities.
- The proposed research is not a clinical trial.
- The proposed project includes preclinical research.
- The PI and/or Partnering PI, if applicable, do not meet the eligibility criteria.
- **Early-Career Investigator Partnering Option:** Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.
- Application failed to address at least one sub-area within one of the two FY26 TBIPHRP CTA Focus Areas.
- An IND or IDE application and/or international equivalent has not been submitted prior to the application submission deadline for a study regulated by a relevant regulatory agency.

### 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"** | ☐ | ☐ |
| **Impact Statement – Attachment 6, upload as "Impact.pdf"** | ☐ | |
| **Regulatory Strategy – Attachment 7, upload as "Regulatory.pdf"** | ☐ | |
| **Post-Award Transition Plan – Attachment 8, upload as "Transition.pdf"** | ☐ | |
| **Study Population Recruitment and Safety Plan – Attachment 9, upload as "StudyPopPlan.pdf"** | ☐ | |
| **Partnership Statement (if applicable) – Attachment 10, upload as "Partnership.pdf"** | ☐ | |
| **Study Personnel and Organization – Attachment 11, upload as "Personnel.pdf"** | ☐ | |
| **CBPR Documentation – Attachment 12, upload as "CBPR.pdf"** | ☐ | |
| **Relevance to Military Health Statement – Attachment 13, upload as "Military.pdf"** | ☐ | |
| **Representations *(Grants.gov submissions only)* – Attachment 14, upload as "RequiredReps.pdf"** | ☐ | ☐ |
| **Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 15, 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 |
| ASR | Acute Stress Response |
| CAB | Community Advisory Board |
| CDE | Common Data Elements |
| CBPR | Community-Based Participatory Research |
| 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 |
| DOW | U.S. Department of War |
| DoDGARs | Department of Defense Grant and Agreement Regulations |
| DOW | U.S. Department of War |
| eBRAP | Electronic Biomedical Research Application Portal |
| EC | Ethics Committee |
| EFIC | Exception From Informed Consent |
| EHR | Electronic Health Records |
| ET | Eastern Time |
| FAD | Funding Authorization Document |
| FDA | U.S. Food and Drug Administration |
| FITBIR | Federal Interagency Traumatic Brain Injury Research |
| FY | Fiscal Year |
| GAI | General Application Instructions |
| IACUC | Institutional Animal Care and Use Committee |
| IDE | Investigational Device Exemption |
| IND | Investigational New Drug |
| IPR | In-Progress Review |
| IRB | Institutional Review Board |
| LEC | Lived-Experience Consultant |
| LOI | Letter of Intent |
| M | Million |
| MIPR | Military Interdepartmental Purchase Request |
| NDA | National Institute of Mental Health Data Archive |

| | |
|---|---|
| NIH | National Institutes of Health |
| NIMH | National Institute of Mental Health |
| NINDS | National Institute of Neurological Disorders and Stroke |
| ORRC | Office of Research and Regulatory Compliance |
| PDF | Portable Document Format |
| PHS | Public Health Service |
| PI | Principal Investigator |
| PTSD | Posttraumatic Stress Disorder |
| R&D | Research and Development |
| RPPR | Research Performance Progress Report |
| SAM | System for Award Management |
| SF424 R&R | Standard Form 424 (Application for Federal Assistance, Research & Related) |
| SOW | Statement of Work |
| SPIRIT | Standard Protocol Items: Recommendations for Interventional Trials |
| STROBE | STrengthening the Reporting of OBservational studies in Epidemiology |
| TBI | Traumatic Brain Injury |
| TBIPHRP | Traumatic Brain Injury and Psychological Health Research Program |
| UEI | Unique Entity Identifier |
| URL | Uniform Resource Locator |
| USC | United States Code |
| VA | U.S. Department of Veterans Affairs |

# Appendix 3: Additional Focus Area Information

The information below in italics provides additional context regarding programmatic intent but **is not required** to be specifically addressed by applications.

1. **Prevent and Assess:** Research will address the prevention, screening, diagnosis, or prognosis of psychological health conditions and/or TBI.
    a. Identification and validation of biomarkers or other objective methods for assessment, diagnosis, prognosis or real-time monitoring of psychological health conditions and/or TBI, including subclinical presentations, and associated sequelae of these conditions.
        - *Development of decision-making frameworks or tools that incorporate objective assessments and may consider long-term outcomes to inform return to activity/duty decisions is within scope*.
    b. Development and evaluation of approaches or tools to prevent or reduce risk of psychological health conditions and/or TBI.
        - *Evaluation of environmental sensor data in aspects related to brain health and risk from brain blast and impact exposures.*
        - *Development of innovative materials and technologies that can prevent or reduce risk of TBI.*
        - *Generation of physiological evidence regarding the safety, efficacy and utility of candidate neuroprotective measures. Animal models, if used, should be validated and well justified within the literature and should demonstrate clear alignment to clinical populations.*
        - *Validation of objective tools/methods for assessing and real-time health status monitoring of psychological health conditions and/or TBI.*
        - *Development of clinical decision-making frameworks or tools that incorporate objective assessments and long-term outcomes to return-to-activity/duty decisions.*
    c. Development and evaluation of crosscutting prevention approaches to address multiple adverse outcomes such as suicide, interpersonal violence including intimate partner and family violence, sexual assault, psychological health issues and/or TBI.
        - *Crosscutting prevention approaches refer to strategies that enhance protective factors and reduce risk factors at multiple socio-ecological levels, (e.g., individual, relationship and community).*
        - *Optimized messaging for successful dissemination and implementation.*
        - *Inclusion of Families and evaluation of Family impact.*
        - *Culturally acceptable approaches to reducing access to lethal means and promoting means safety for suicide and violence prevention.*
    d. Development and evaluation of solutions to support military and Family readiness and increase psychological resilience in individuals to the potential negative impacts of specific military and life stressors.

- *Military readiness refers to the ability of military forces to fight and meet the demands of national military strategy; Family readiness is the state of preparedness to effectively navigate the challenges of daily living experienced in the unique context of military service.*
- *Effective pharmacologic or non-pharmacologic prevention interventions. Solutions for prevention of acute stress reactions (ASRs) and PTSD or adjustment disorders may be proposed.*
- *Preparation of Service Members and units for missions and to help reset and improve resilience between deployments.*
- *Effective solutions to support relationships and parenting, prepare Families for potential secondary trauma exposure, and empower Families to access tailored support and resources.*

2. **Treat:** Research will address novel and repurposed interventions to improve the outcomes of psychological health conditions and/or TBI. Efforts that address treatment, rehabilitation and health services research are within scope.
   a. Interventions that promote sustained functional recovery, including interventions administered acutely or during the post-acute phase or chronic phase of injury.
      - *Rapid assessments and treatments for psychological health conditions. Interventions addressing adjustment disorders, ASRs and PTSD may be proposed.*
      - *Mobile health technologies to improve mental health and well-being.*
      - *Interventions focused on sensory and motor dysfunction after brain injury.*
      - *Interventions that address neurodegenerative processes associated with TBI.*
      - *Interventions that restore cognitive reserve and functioning.*
      - *Novel therapeutic candidates based on evolving changes of pathophysiology and/or theoretical mechanisms of psychological health conditions and/or TBI.*
      - *Interventions and/or the delivery of health care services to improve the ability to treat co-occurring TBI and psychological health conditions.*
      - *Personalized medicine approaches to treatment that may include tailoring treatment to the biological and endophenotypic elements present. Treatment approaches may consider how TBI, PTSD, depression, or other psychological health conditions are interrelated.*
      - *Considerations for sequencing and optimal combinations of pharmacologic and non-pharmacologic interventions.*
      - *Effective, early interventions for delivery in rural or other resource-limited environments (e.g., far-forward military environments), and/or by non-clinicians (e.g., peers, teams, first responders/medics).*

b. Development of postvention strategies to support individuals in workplace or community environments following a sexual assault, suicide event or other trauma.

   - *Postvention refers to response activities that should be undertaken in the immediate aftermath of a suicide that has impacted the unit. Postvention has two purposes: to help suicide attempt survivors cope with their grief, and to prevent additional suicide.*

c. Health services research to improve the adoption of evidence-based practices, access to care, or reduce barriers to care. Individual and systemic factors that influence access to or barriers to care as well as other factors that influence treatment engagement, follow-up care and improvement of long-term outcomes are applicable.

   - *Research of interest includes, but is not limited to, individual, peer/unit/team, leader, family, caregivers, community and enterprise level methods.*
   - *Clinical effectiveness studies comparing emerging capabilities to existing evidence-based treatments and/or the standard of care.*
   - *Identification and evaluation of methods for successful dissemination and implementation of intervention.*

# Appendix 4: Optimizing Research Impact Through Community Collaboration

CBPR supports collaborative research that involves scientific researchers and community members working together to address diseases and conditions, particularly those that disproportionately affect health disparity populations. Recognizing the strength of each partner, scientific researchers and community members ***collaborate and contribute equitably their expertise in all aspects of the project, which may include a needs assessment, planning, research intervention design, implementation, evaluation and dissemination.*** CBPR features shared responsibility for and ownership of the research project, and the research results are jointly interpreted, disseminated and fed back to affected communities and may be translated into interventions or policy. CBPR methods are critically important for community-level interventions and conditions affecting health disparity populations. CBPR methods, such as collaborative planning, data collection, analysis/interpretation, dissemination and implementation, actively engage consumers and communities in research. These interactions can accelerate “bench--to bedside” translation and augment the potential impact of research on people living with psychological health conditions and/or TBI.

CBPR collaborative relationships are often established through integrating community members into research teams as co-researchers, advisors and consultants. Some examples of CBPR collaborations include:

- Lived-Experience Consultants (LECs)/consumers: The research team includes at least one member with lived psychological health conditions and/or TBI experience who will provide advice and consultation throughout the planning and implementation of the research project. LECs may include individuals with a TBI or psychological health condition, their family members, or care partners. Ideally, a LEC should be an individual(s) nominated by a foundation or advocacy group in order to represent those with TBI or psychological health conditions versus individual experiences.
- Partnership with a community-based organization: The research team establishes partnerships with at least one community-based organization that provides advice and consultation throughout planning and implementation of the research project. Community-based organizations may include advocacy groups, service providers, policymakers, or other formal organizational stakeholders.
- Community Advisory Board (CAB): A CAB is composed of multiple community stakeholders and can take many forms, from a board of LECs to a coalition of community-based organizations or any combination thereof. As with LECs and organizational partners, the CAB provides advice and consultation throughout planning and implementation of the research project.

Additional information on CBPR can be found here:

- B. Chung et al., "Using a Community Partnered Participatory Research Approach to Implement a Randomized Controlled Trial: Planning the Design of Community Partners in Care," *Journal of Health Care for the Poor and Underserved* 21, no. 3 (2010): 780–95. doi: 10.1353/hpu.0.0345.
- N. Wallerstein and B. Duran, "Community-Based Participatory Research Contributions to Intervention Research: The Intersection of Science and Practice to Improve Health Equity," *American Journal of Public Health* 100, no. S1 (2010): S40–S46. doi: 10.2105/AJPH.2009.184036.

- Patient-Centered Outcomes Research Institute's Engagement Tool and Resource Repository, https://www.pcori.org/engagement/engagement-resources/Engagement-Tool-Resource-Repository.
- S.E. Collins et al., "Community-Based Participatory Research (CBPR): Towards Equitable Involvement of Community in Psychology Research," *American Psychologist* 73, no. 7 (2018): 884–98. doi: 10.1037/amp0000167.
- Oetzel JG, Boursaw B, Littledeer L, Kastelic S, et al. (2025). A short pragmatic tool for evaluating community engagement: Partnering for Health Improvement and Research Equity. Front Public Health. 2025 Jun 11;13:1539864. doi: 10.3389/fpubh.2025.1539864.