I. OVERVIEW OF THE FUNDING OPPORTUNITY

Broad Agency Announcement for Extramural Research (Program Specific) for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Traumatic Brain Injury and Psychological Health Research Program

Clinical Trial Award

Announcement Type: Initial

Funding Opportunity Number: HT942524STBIPH1

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application/Proposal Submission Deadline:** 5:00 p.m. Eastern time (ET), June 27, 2024

  Invitation to Submit an Application: August 8, 2024

- **Full Application/Proposal Submission Deadline:** 11:59 p.m. ET, October 3, 2024
- **End of Submission Verification Period:** 5:00 p.m. ET, October 8, 2024
- **Peer Review:** December 2024
- **Programmatic Review:** February 2025

This Broad Agency Announcement must be read in conjunction with the General Submission Instructions available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

This funding opportunity announcement is a Broad Agency Announcement (BAA) through the fiscal year 2024 (FY24) Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP) for the Clinical Trial Award (CTA). For the remainder of the announcement, this BAA will be referenced as the FY24 TBIPHRP CTA. Specific submission information and additional administrative requirements can be found in the document titled "General Submission Instructions," available in Grants.gov along with this BAA.

This BAA for the TBIPHRP is intended to solicit extramural research and development ideas using the authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). This BAA is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 and in Department of Defense Grant and Agreement Regulations (DoDGARs) 22.315. In accordance with FAR 35.016, projects funded under this BAA must be for *applied research* not related to the development of a specific system or hardware procurement. Research and development funded through this BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge.

This BAA is intended for extramural applicants only. **For definitions and additional information, see** Section II.C.1, Eligible Applicants**.** The North American Industry Classification System code for contracts under this announcement is 541715 with a small business size standard of 1,000 employees.

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the FY24 TBIPHRP CTA using delegated authority provided by 10 USC 4001. The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. In FY07, Congress appropriated funding for traumatic brain injury (TBI) and psychological health research in response to the TBIs sustained and psychological health issues experienced by our deployed forces in Iraq and Afghanistan. The TBIPHRP complements ongoing Department of Defense (DOD) 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 FY23 totaled $2.4 billion (B). The FY24 appropriation is $175.0 million (M).

The TBIPHRP's vision is to optimize the prevention, assessment, and treatment of psychological health conditions and/or traumatic brain injuries (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 and health care of Service Members, their Families, Veterans, and the American public. ***Proposed research can be aligned with TBI, psychological health, or in combination.***

II.A.1. FY24 TBIPHRP Clinical Trial Award (CTA) Focus Areas

To meet the intent of the award mechanism, proposals/applications ***must address at least one sub-area (1a, 2a, 2b, etc.)*** within one of the two FY24 TBIPHRP CTA Focus Areas listed below. Bulleted items are provided in Appendix 4 to indicate additional context regarding programmatic intent but are not required to be specifically addressed by applications. ***Proposed research must be hypothesis-driven and can be aligned with TBI, psychological health, or in combination.*** Proposals/applications consisting solely or primarily of planning, engineering, manufacturing, or formulation activities may be administratively withdrawn. Selection of the appropriate FY24 TBIPHRP CTA Focus Area is the responsibility of the applicant.

Inclusion of 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 General Submission Instructions Appendix 2, Section E.

This BAA may not be used to support studies requiring an exception from informed consent (EFIC).

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[1] to address multiple adverse outcomes such as suicide, interpersonal violence (including intimate partner and family violence), and psychological health issues are within scope.

[1] 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). https://www.sapr.mil/sites/default/files/PPoA_2.0.pdf

d. Development and evaluation of solutions to support military and family readiness[2] and increase psychological resilience in individuals to the potential negative impacts of specific military and life stressors.

2. **Treat:** Research will address novel and repurposed interventions[3] to improve 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 during the chronic phase of injury.

   b. Development of postvention[4] strategies to support individuals in workplace or community environments following a sexual assault, suicide event, or other trauma.

   c. Health services research to improve provider adoption of evidence-based practices, improve access, and reduce barriers. In addition, factors that influence treatment engagement, follow-up care, and improvement of long-term outcomes are of interest.

II.A.2. Award History

The TBIPHRP CTA Award mechanism was first offered in FY21. Since then, 238 CTA application/proposals have been received, and 83 have been recommended for funding.

II.B. Award Information

The intent of the FY24 TBIPHRP CTA is to support the rapid implementation of clinical trials with the potential to have a significant impact on psychological health conditions and/or TBI through clinical applications, including health care products, technologies, and/or practice guidelines. ***Proposed research can be aligned with TBI, psychological health, or in combination.***

Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs or biologics), diagnostics, devices, therapies, clinical guidance, behavioral interventions, emerging approaches and technologies, and/or new indications for products currently U.S. Food and Drug Administration (FDA)-approved or -cleared. Interventions that are not FDA-regulated (or international equivalent) are within scope but the regulatory status must be documented in Attachment 8, Regulatory Strategy. Proposed projects may range from small proof-of-concept trials (e.g., pilot, first-in-human, phase 0) to demonstrate feasibility or

[2] Military readiness is the ability of military forces to fight and meet the demands of assigned missions. Family readiness is the state of being prepared to effectively navigate the challenges of daily living experienced in the unique context of military service. https://www.tradoc.army.mil/wp-content/uploads/2020/10/AD1029823-DOD-Dictionary-of-Military-and-Associated-Terms-2017.pdf

[3] Intervention repurposing is the identification of novel indication(s) for an FDA-approved intervention.

[4] For the TBIPHRP, "postvention" is defined the response to and care for individuals affected in the aftermath of a sexual assault, suicide event, or other trauma" (adapted from U.S. Department of Health and Human Services Office of the Surgeon General and National Action Alliance for Suicide Prevention, 2010, p. 141).

inform the design of more advanced trials through large-scale trials to determine efficacy in relevant patient populations.

Funding from this award mechanism must support a clinical trial. A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For more information, a Human Subject Resource Document is provided at https://cdmrp.health.mil/pubs/pdf/Human%20Subjects%20Resource%20Document_DEC2022.pdf.

Principal Investigators (PIs) proposing comparative effectiveness, implementation science, health care services research as the primary research objective should consider the ***FY24 TBIPHRP Health Services Research Award (Funding Opportunity Number HT942524TBIPHRPHSRA).*** PIs seeking funding for a preclinical research project should consider one of the other FY24 TBPHRP program announcements.

Key aspects of the FY24 TBIPHRP CTA:

- **Clinical Trial Start Date:** The proposed clinical trial is expected to begin no later than 6 months after the award date for studies regulated by the Regulatory Agency.

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

- **Community-Based Participatory Research:** The application/proposal **must** include Community-Based Participatory Research (CBPR) approaches in the development and execution of the clinical trial. CBPR approaches should be documented in Attachment 13.

- **Study Population:** The application should demonstrate the availability of and access to a suitable patient population that will support a meaningful outcome for the study. The application should include a discussion of how accrual goals will be achieved, as well as the strategy for inclusion of women and minorities in the clinical trial appropriate to the objectives of the study. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

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

- **Personnel and Environment:** The application/proposal should demonstrate the study team's expertise and experience in all aspects of conducting clinical trials, including

appropriate statistical analysis, knowledge of Regulatory Agency processes (if applicable), and data management. The application/proposal should include a study coordinator(s) who will guide the clinical protocol through the local IRB of record and other federal agency regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual. The application/proposal should show strong institutional support and, if applicable, a commitment to serve as the regulatory sponsor, ensuring all sponsor responsibilities described in 21 CFR 312, Subpart D, for FDA-regulated studies.

- **Innovative Clinical Trial Design:** When appropriate, the TBIPHRP encourages the use of innovative clinical trial design approaches (e.g., Bayesian, adaptive, clinical bioequivalence, seamless, exploratory/phase 0, basket, stepped wedge) that improve efficiency and ability to determine clinical benefit while maintaining validity, integrity, and ethical considerations.

- **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.

- **Statistical Analysis and Data Management Plans:** The application/proposal should include a clearly articulated statistical analysis plan, a power analysis reflecting sample size projections that will answer the objectives of the study, and a data management plan that includes use of an appropriate database to safeguard and maintain the integrity of the data. If required by a Regulatory Agency, the trial must use a 21 CFR 11-compliant database and appropriate data standards.

For the purposes of this funding opportunity Regulatory Agency refers to the FDA or any relevant international regulatory agency unless otherwise noted.

If the proposed clinical trial involves the use of a drug that has not been approved by the relevant Regulatory Agency for the country where the research will be conducted, then submission of an Investigational New Drug (IND) application, or equivalent, that meets all requirements under 21 CFR 312 may be required.

- It is the responsibility of the applicant to provide evidence from the IRB of record or the relevant Regulatory Agency if an IND, or equivalent, is not required. If an IND, or equivalent, is required, the regulatory application ***must be approved/cleared/authorized or submitted to the relevant Regulatory Agency within the first 60 days of the award.***

- The investigational drug application, or equivalent, should be specific for the product and indication to be tested in the proposed clinical trial. For more information on FDA IND applications specifically, the FDA has provided guidance at https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application.

If the investigational product is a device, then submission of an Investigational Device Exemption (IDE), or equivalent, application that meets all requirements under 21 CFR 812 may be required.

- It is the responsibility of the applicant to provide evidence if an IDE, or equivalent, is not required. If an IDE, or equivalent, is required, the IDE application, or equivalent, ***must be***

approved/cleared/authorized or submitted to the relevant Regulatory Agency within the first 60 days of the award.

- The investigational device application, or equivalent, should be specific for the device and indication to be tested in the proposed clinical trial. For more information on FDA IDE applications specifically, the FDA has provided guidance at https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide.

If the proposed clinical trial of an investigational product will be conducted at international sites, evidence that an application to the relevant national regulatory agency of the host country(ies) ***has been approved/cleared/authorized or submitted within the first 60 days of the award*** within Attachment 8, Regulatory Strategy.

Research Levels: The following are general descriptions, although not all-inclusive, of the scope of research projects that would be appropriate to propose under the current BAA. Only one Research Level category may be chosen per application. It is the responsibility of the applicant to select the level that aligns with the scope of the proposed research. The Research Level should be selected based on the research scope and not on the amount of the budget. Refer to Section II.D.6, Funding Restrictions, for detailed funding information.

- **Research Level 1:** Research Level 1 is intended to support proof-of-principle pilot studies, phase 0/small phase 1 trials, correlative studies related to an intervention, and other innovative, exploratory clinical trials. The maximum period of performance is **3** years. The application/proposal's ***direct*** costs budgeted for the entire period of performance should not exceed **$500,000**.

    - **Early-Career Investigator Partnering Option:** The FY24 TBIPHRP CTA (Research Level 1 only) includes an Early-Career Investigator Partnering Option that is structured to accommodate two PIs, one of whom is an Early-Career Investigator. The ***combined direct costs*** budgeted for the entire period of performance in the proposals/applications of the ***Initiating PI and Partnering PI should not exceed $500,000.***

        - The PIs may have experience in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application/proposal. One PI will be identified as the Initiating PI and will be responsible for most of the administrative tasks associated with application/proposal submission. The other investigator will be the Partnering PI. ***At least one of the Initiating or Partnering PIs must be an Early-Career Investigator.***

        - The intent is not to create mentor-mentee arrangement. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. The application/proposal is expected to describe how the PIs' unique experience/expertise combined as a partnership will better address the research question, how the unique experience/expertise that each individual brings to the application/proposal is critical

for the research strategy and completion of the SOW, and why the work should be done together rather than through separate efforts.

  - If recommended for funding, each PI will be named to an individual award within the recipient organization(s). For individual DOD FY24 TBIPHRP CTA submission requirements for the Initiating and Partnering PI, refer to Section II.D.2, Content and Form of the Application/proposal Submission.

- **Research Level 2:** Research Level 2 is intended to support phase 1 and more advanced clinical trials for promising interventions. The maximum period of performance is **4** years. The application/proposal's ***direct costs*** budgeted for the entire period of performance should not exceed **$2.0M**.

- **Research Level 3:** Research Level 3 is intended to support larger-scale clinical trials that demonstrate efficacy in relevant patient populations. The maximum period of performance is **4** years. The application/proposal's ***direct costs*** budgeted for the entire period of performance should not exceed **$4.0M.**

Relevance to Military Health: Relevance to the health care needs of Service Members, their Families, and Veterans is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate relevance to military health:

- Explanation of how the project addresses an aspect of psychological health conditions and/or TBI that has direct relevance to the health and/or readiness of Service Members, their Families, and Veterans.

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

- Use of military or Veteran populations, samples, or datasets in the proposed research, if appropriate.

Collaborations between researchers or consultants at military or Veterans organizations and non-military organizations are encouraged. These relationships can leverage knowledge, infrastructure, and access to unique data and research resources that the partners bring to the research effort, ultimately advancing TBI and psychological health research of significance to Service Members, their Families, and Veterans. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 2.

Use of DOD or VA Resources: If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to Section II.D.2.b.iii., Full Application Submission Components for the Partnering PI, for detailed information. Refer to the General Submission Instructions, Appendix 1, Section C for additional information. ***Note, the CDMRP will not serve as the***

government sponsor or signatory on any access applications or agreements for DOD or VA patient populations, resources, or databases.

Conducting DOD-Funded Human Research with Military Populations: There are unique requirements and prohibitions for compensating DOD-affiliated personnel for study participation and for conducting research with military families/children and U.S. Army Special Operations Command populations. Additional information regarding conducting DOD-funded human research with military populations can be found at https://cdmrp.health.mil/pubs/pdf/Conducting%20Research%20Military%20Pop%20DoD_funded_7NOV2022.pdf.

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

Women's Health: The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Optimizing Research Impact Through Community Collaboration: Research funded by the FY24 TBIPHRP should be responsive to the psychological health conditions and/or TBI needs of the lived experience/consumer, family, and care provider communities. Through the establishment and utilization of effective and equitable collaborations and partnerships, the translational and impact potential of the proposed research can be maximized. ***For the FY24 TBIPHRP CTA, inclusion of CBPR approaches is required*** and should be documented in Attachment 13, CBPR Documentation.

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 on 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/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. Lived Experience Consultants (LECs) may include individuals with a TBI or psychological health condition, their family members, or care partners. Ideally an LEC should an individual(s) nominated by a foundation or advocacy group in order to represent the diversity of those with TBI or psychological health conditions vs. 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 LEC 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:

- Chung B, Jones L, Dixon EL, et al. 2010. 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(3):780-795. doi: 10.1353/hpu.0.0345.

- Wallerstein N and Duran B. 2010. Community-based participatory research contributions to intervention research: The intersection of science and practice to improve health equity. *American Journal of Public Health* 100(S1):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.

- Toolkit to Better Understand and Measure Stakeholder Engagement, https://pstrapiubntstorage.blob.core.windows.net/strapib/assets/ICDR_ACL_Stakeholder_Toolkit_071922_508_a966ea809b.pdf.

Data Sharing Requirement 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 (including both the scientific and consumer advocacy communities) and the public at large. Note that the CDMRP will not serve as the government sponsor or signatory on any data-sharing agreements. For additional guidance, refer to the General Application Instructions, Appendix 2, Section L.

- **All Prospective Human Subject Research**

  - Applicants ***must*** include language in informed consent documents to allow for submission of de-identified data to a repository or for secondary use/meta-analyses of the data.

  - Applicants are also strongly encouraged to include language in consent forms to enable optional passive follow-up via electronic health record.

  - ***The TBIPHRP requires applicants to incorporate Common Data Elements (CDEs) appropriate to each field of study*** such as the PhenX Core and Specialty collections and National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs. ***Justification is required*** if CDEs are not utilized.

  - As applicable, applicants are strongly encouraged to include secondary outcomes in proposed studies to address potential crosscutting impacts.

  - As appropriate, the inclusion of TBI, psychological health, and caregiver/family outcomes measures is encouraged, regardless of the primary focus of the study.

- **Psychological Health Research**

  - The TBIPHRP requires that all psychological health-related clinical research data with at least 50 subjects funded by this program be shared through the National Institute of Mental Health (NIMH) Non-Disclosure Agreement (NDA). The NDA provides an infrastructure for sharing research data, tools, methods, and analyses enabling collaborative science and discovery. The NDA mission is to accelerate scientific research and discovery through data sharing, data harmonization, and the reporting of research results. Consult the NDA website at https://nda.nih.gov/ for additional information.

  - While there is no direct charge to users of the NDA, a project estimation tool is available to help estimate costs and manpower needs that may be associated with data submission.

- **Traumatic Brain Injury Research**

  - The TBIPHRP requires that all TBI-related clinical research data with at least 50 subjects funded by this program be shared through the jointly supported DOD-NIH Federal Interagency TBI Research Information System (FITBIR). Recipients will be required to upload study data annually and in accordance with the FITBIR data submission policies. There is no fee to use FITBIR, and detailed guidance and policies, including a cost estimator tool for budgeting considerations, can be found at https://fitbir.nih.gov.

  - While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool is available to help estimate costs and manpower needs that may be associated with data submission.

- **Traumatic Brain Injury Research and Psychological Health Research**
    - Applicants proposing to conduct research collecting both TBI and psychological health human subject data may follow the requirements for either TBI research, psychological health research, or both as appropriate. Applicants should justify their choice.

The funding instrument for awards made under the announcement will be assistance agreements, or contracts. The type of instrument used to reflect the business relationship between the organization and the government is at the discretion of the government, in accordance with the Federal Grant and Cooperative Agreement Act of 1977, as amended, 31 USC 6301-6308, which provides the legal criteria to select a procurement contract or an assistance agreement.

An **assistance agreement** can take the form of a **grant** or **cooperative agreement**. The level of involvement on the part of the CDMRP during the project's period of performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of the CDMRP is anticipated, a grant will be made (31 USC 6304). Conversely, if "substantial involvement" on the part of the CDMRP is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement means that, after award, CDMRP staff will assist, guide, coordinate, or participate in project activities including but not limited to:

- Making recommendations for continued funding based on (a) overall study progress, including sufficient patient and/or data accrual; (b) cooperation in carrying out the research (e.g., implementation of group decisions, compliance with the terms of award and reporting requirements); and/or (c) maintenance of a high quality of research.

A contract is required when the principal purpose of the instrument is to acquire property or services for the direct benefit or use of the U.S. government.

The award type, along with the start date, will be determined during the negotiation process.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $58.9M to fund approximately 4 Research Level 1, 10 Research Level 2, and 4 Research Level 3 FY24 TBIPHRP CTA proposals/ applications. Funding of applications/proposals received is contingent upon the availability of federal funds for this program, the number of applications/proposals received, the quality and merit of the applications/proposals 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. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants/Offerors

II.C.1.a. Organization

Applications/proposals for this BAA may only be submitted by extramural organizations, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities. Submissions from intramural DOD organizations to this BAA will be withdrawn.

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

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

Applications/proposals with PIs employed by intramural DOD organizations may be submitted extramurally through a research foundation. It is also permissible for an intramural DOD investigator to be named as a collaborator on an application/proposal submitted through an extramural organization. In this case, the submission must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

In accordance with DoDI 5000.77, Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this BAA. However, teaming arrangements between FFRDCs and eligible organizations are allowed as long as they are permitted under the sponsoring agreement between the federal government and the specific FFRDC.

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

II.C.1.b. Principal Investigator

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

II.C.1.b.i. Single PI Option

Principal Investigator: Independent investigators at all academic/career levels (or equivalent) may be named by organizations as the PI on the application. For titles outside of academia that may not be analogous to traditional hierarchies, investigators at or above an independent scientist level may be named by their organization as the PI on the application. ***Postdoctoral fellows are not considered independent investigators.***

II.C.1.b.ii. Early-Career Investigator Partnering Option

For proposals/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/proposal 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 proposal/application. For Early-Career Investigator Partnering Option applications, at least one of the named PIs ***must*** be an Early-Career Investigator.

Postdoctoral fellows are not considered independent investigators.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement for contracts or assistance agreements.

II.C.3. Other

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

Use of the System for Award Management (SAM): To protect the public interest, the federal government ensures the integrity of federal programs by striving to conduct business only with responsible organizations. The USAMRDC uses the "Exclusions" within the Performance Information functional area of the SAM and the "Responsibility and Qualifications" within the Entity Information functional area of the SAM to verify that an organization is eligible to receive federal awards. More information about SAM is available at https://sam.gov/SAM/. Refer to the General Submission Instructions, Appendix 1, for additional information.

Conflicts of Interest (COIs): Prior to award, applicants/offerors will be required to disclose all potential or actual COIs along with a plan to mitigate them. An award may not be made if it is determined by the USAMRAA Warranted Official that COIs cannot be adequately mitigated. Refer to the General Submission Instructions, Appendix 1, for additional information.

Review of Risk: The following areas may be reviewed in evaluating the risk posed by an applicant/offeror: financial stability; quality of management systems and operational controls; history of performance; reports and findings from audits; ability to effectively implement statutory, regulatory, or other requirements imposed on non-federal entities; degree of institutional support; integrity; adequacy of facilities; and conformance with safety and environmental.

Subcontracting Plan: If the resultant award is a contract that exceeds $750,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7, Defense Federal Acquisition Regulation Supplement (DFARS) 219.7. A mutually agreeable plan will be developed during the award negotiation process and incorporated as part of the resultant contract.

Refer to Section II.H.1, Administrative Actions, for a list of administrative actions that may be taken if a pre-application /proposal or full application/proposal does not meet the administrative, eligibility, or ethical requirements defined in this BAA.

II.D. Application/Proposal and Submission Information

II.D.1. Location of Application/Proposal Package

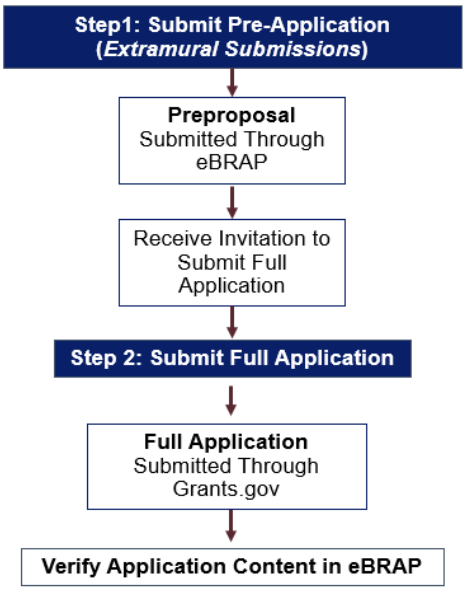
Submission is a two-step process requiring both a ***pre-application/proposal*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application/proposal*** submitted through eBRAP.org or Grants.gov.

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

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives to receive communications from the CDMRP and submit their pre-applications/proposals. Additionally, eBRAP allows applicants/offerors to view and verify full applications/proposals submitted to Grants.gov.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant opportunities. Full applications/proposals for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application/proposal through eBRAP.

Application Submission Workflow



Extramural Submission: An application/proposal submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural DOD organization. For example, a research foundation submitting an application for a DOD employee working

within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application/proposal package components for HT942524STBIPH1 from Grants.gov (https://grants.gov). Full applications/proposals from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission *(Disallowed for this funding opportunity)*: An application/proposal submitted by an intramural DOD organization for an investigator employed by that organization.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application/proposal components must be submitted by the deadlines stipulated on the first page of this BAA. There are no grace periods for deadlines; failure to meet submission deadlines will result in application/proposal rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant/offeror organization using system-to-system interfaces with Grants.gov.***

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

Applications/proposals 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)/proposal(s).

Unnecessary duplication of funding or accepting funding from more than one source for the same research, is prohibited. See the CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

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

FY24 TBIPHRP Programmatic Panel members should not be involved in any pre-application/proposal or full application/proposal. For questions related to panel members involvement, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

All pre-application components must be submitted by the PI or Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for the Partnering PI if exercising the Research Level 1 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 each PI, the Business Official(s), performing organization(s), and contracting organization(s) must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP.

If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

Research Level 1-Early Career Investigator Partnering Option: After the Initiating PI confirms submission of the pre-proposal/pre-application, the Partnering PI will be notified of the pre-proposal/pre-application submission via an email from eBRAP. ***The Partnering PI must follow the link in the notification email to associate the partnering pre-proposal/pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

After associating the pre-proposal/pre-application with their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-proposal/pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-proposal/pre-application (extramural or intramural).

Partnering PIs should not initiate a new pre-proposal/pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to complete these steps as soon as possible. If they are not completed:

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

When starting the pre-proposal/pre-application, applicants will be asked to select a "Mechanism Option". Please be sure to select the correct option appropriate to your pre-application:

Application/Proposal Includes:	Select Option:
Single PI	No Option
Initiating PI and Early-Career Investigator Partnering PI	Early-Career Investigator Partnering
Early-Career Investigator Initiating PI and Partnering PI	Early-Career Investigator Partnering

II.D.2.a.i. Pre-Proposal/Pre-Application Components

The pre-proposal/pre-application consists of the following components (refer to the General Submission Instructions, Section II, for additional information on pre-proposal/pre-application submission):

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

- **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource

locators) that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-proposal/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 FY24 TBIPHRP CTA Focus Areas.

- **Rationale:** Briefly describe the scientific rationale, intervention (non-pharmacological interventions, diagnostics, devices, therapies, clinical guidance, behavioral interventions are also within scope) and intervention's readiness to support the initiation of the proposed clinical trial; include relevant preliminary data and literature citations. Identify the phase of the clinical trial proposed. Briefly describe the intended subject population(s). Identify and justify the requested research level. 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.

- **Specific Aims and Study Design:** Concisely state the project's hypothesis and/or objectives and specific aims. Specific aims should be independent and not depend on the successful completion of prior aims. Briefly describe the experimental approach, including study design and endpoints/outcome measures.

- **Research Team:** Briefly state the qualifications and expected contributions of the PI(s) and key personnel to perform the clinical trial. Note any DOD or VA collaborations. Explain how the project incorporates CBPR.

- **Impact and Relevance to Military Health:** Describe how the proposed work will have an impact on accelerating the movement of promising research into clinical application. Explain how the project is relevant to the health care needs of Service Members, their Families, and/or Veterans.

- **Pre-Proposal/Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-proposal/pre-application ***must be uploaded as individual files*** and are limited to the following:

  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

  - **Key Personnel Biographical Sketches (six-page limit per individual):** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and experience/expertise through education, positions, publications, and previous work accomplished.

Biographical sketches, or equivalent document, should also be included for LEC 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.)

II.D.2.a.ii. Pre-Proposal/Pre-Application Screening Criteria

To determine the technical merits of the pre-proposal/pre-application and the relevance to the mission of the Defense Health Program (DHP) and the TBIPHRP, pre-proposals/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 FY24 TBIPHRP CTA Focus Areas.
- **Rationale:** How well the scientific rationale is supported, and how well the scientific evidence, readiness, and availability of and accessibility to resources and subject population indicates that the research is appropriate for the research level requested.
- **Specific Aims and Study Design:** How well the specific aims, study design, and experimental approach will address the hypothesis and/or reach the desired objectives.
- **Research Team:** How the qualifications and expected contributions of the PI(s) and other key personnel are appropriate to successfully complete the clinical trial. How well the research incorporates CBPR.
- **Impact and Relevance to Military Health:** The degree to which the proposed clinical trial will have an impact on accelerating the movement of promising research into clinical application. How well the research is relevant to the health care needs of Service Members, their Families, and/or Veterans.

II.D.2.a.iii. Notification of Pre-Proposal/Pre-Application Screening Results

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 I, Overview of 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.

II.D.2.b. Step 2: Full Application/Proposal Submission

II.D.2.b.i. Full Application/Proposal Submission

Full applications/proposals ***must*** be submitted through Grants.gov Workspace. Full applications/proposals from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Submission Instructions,

Section IV, for considerations and detailed instructions regarding full application/proposal submission.

II.D.2.b.ii. Full Application/Proposal Submission Components for the PI or Initiating PI

Research Level 1 Early-Career Investigator Partnering Option: In order to make separate awards to each PI, the CDMRP requires separate full application/proposal package submissions for the Initiating PI and the Partnering PI, even if the PIs are located within the same organization. The Initiating and Partnering PI will each be assigned a unique eBRAP log number. Each full application/proposal package must be submitted using the unique eBRAP log number. ***Note: All associated proposals/applications (Initiating PI's and the Partnering PI's) must be submitted by the full application/proposal submission deadline.***

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

Each submission must include the completed full application/proposal package for this BAA. See Section II.H.2 of this BAA for a checklist of the required components.

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

(b) Attachments:

Each attachment to the full application/proposal components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Submission Instructions, Appendix 2.

- **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application/proposal.

  The Project Narrative is NOT the formal clinical trial protocol. Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 6–13 described below. Failure to submit these attachments as part of the application/proposal package will result in rejection of the entire application/proposal.

  Describe the proposed project in detail using the outline below.

  - **Background:** The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the study and explain the applicability of the proposed findings to the intent of the mechanism and selected

sub-area(s) within one of the two FY24 TBIPHRP CTA Focus Areas. Describe in detail the scientific rationale for the study and include a literature review, unpublished data, preliminary studies, and/or preclinical data that support the development of the proposed clinical trial and justifies the research level requested. Provide a summary of other relevant ongoing, planned, or completed clinical trials and describe how the proposed study differs. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable). 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 13.***

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

- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study. State the specific aims and hypotheses and their relevance to the study purpose and objectives. Specific aims should be independent and not depend on the successful completion of prior aims. The aims should align with the associated tasks described in the SOW (Attachment 5).

- **Study Design:** Describe the type of study to be performed (e.g., treatment, prevention, diagnostic), the study phase or class (if applicable), and the study model (e.g., single group, parallel, crossover). Outline the proposed methodology in sufficient detail to show a clear course of action.

  - Describe how the proposed project is feasible and will be completed within the proposed performance period.

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

  - Define the primary, secondary, or interim endpoints/outcome measures, outline their appropriateness to the proposed research, and describe how and when they will be measured. Include a description of appropriate controls. If the study design (e.g., selection of outcome measures) was guided by communications/ interactions with a Regulatory Agency, please describe. Outline the timing and procedures planned during the follow-up period.

  - Describe the study population, criteria for inclusion/exclusion, and the methods used for recruitment/accrual of human subjects, specimens, or human-based resources.

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

  - Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block

randomization, stratified randomization, age-matched controls, alternating group, or other procedures) and how it meets the needs of the proposed clinical trial. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).

- Outline whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.
- If using psychometric measures, describe their reliability and validity.
- If using herbal medicines or nutritional supplements, describe the proposed measures to ensure consistency of dosing of active ingredients.
- Describe potential problem areas and discuss alternative methods/approaches that may be employed to overcome them. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.

– **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. For phase 3 clinical trials, describe plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

– **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

– **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support (three-page limit per letter is recommended):** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the BAA, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Commitment *(if applicable)* (two-page limit per letter is recommended):** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration *(if applicable)* (two-page limit per letter is recommended):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **Intellectual Property:** Information can be found in 2 CFR 200.315, "Intangible Property."

    - **Background and Proprietary Information:** All software and data first produced under the FY24 TBIPHRP CTA are subject to a federal purpose license. A term of the FY24 TBIPHRP CTA requires the recipient to grant the government all necessary and appropriate licenses, which could include licenses to background and proprietary information that have been developed at private expense.

Therefore, it is important to disclose/list any intellectual property (software, data, patents, etc.) that will be used in performance of the project or provide a statement that none will be used. If applicable, all proprietary information to be provided to the government should be stated and identified; the applicant should indicate whether a waiver of the federal purpose license will be required.

- **Intellectual and Material Property Plan:** Provide a plan for resolving intellectual and material property issues among participating organizations.

– **Data and Research Resources Sharing Plan:** Describe how data or resources generated during the performance of the project will be shared with the research community, including the sharing of de-identified data with repositories. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's expectations for making data and research resources publicly available. NIH-supported Data Repositories can be found at https://www.nlm.nih.gov/NIHbmic/domain_specific_repositories.html.

- ***For applications involving FITBIR-eligible TBI research:***

  - Identify and describe the planned NINDS TBI CDEs, alignment to FITBIR data elements and forms, and timelines for integrating data to the FITBIR Informatics System. Provide a justification as to why existing CDEs are not applicable or appropriate.

  - Provide a justification as to why existing CDEs are not applicable or appropriate.

  - For applications not using FITBIR, please justify and identify the alternative data-sharing platform.

- ***For applications involving NIMH NDA-eligible psychological health research:***

  - Identify and describe the planned CDEs appropriate to each field of study, data elements and forms, and timelines for integrating data to the NIMH NDA.

  - Provide a justification as to why existing CDEs are not applicable or appropriate.

  - For applications not using NIMH NDA, please justify and identify the alternative data-sharing platform.

– **Use of DOD Resources *(if applicable)*:** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

- **Use of VA Resources *(if applicable)*:** Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated nonprofit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **Quad Chart:** Provide a Quad Chart for the proposed project. The format for the Quad Chart is available on the eBRAP "Funding Opportunities & Forms" web page at (https://ebrap.org/eBRAP/public/Program.htm).

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

  The structured technical abstract should be clear and concise and, at a minimum, provide the following information:

  - **Background:** Present the ideas and rationale behind the proposed clinical trial, including sufficient scientific evidence to support the proposed stage of research.

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

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

  - **Study Design:** Identify the phase of the clinical trial and briefly describe the study design, including research participant population(s) and appropriate controls.

  - **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 FY24 TBIPHRP CTA Focus Areas to be addressed. Describe how the research aligns with the intent of the FY24 TBIPHRP CTA.

  - **Relevance to Military Health:** Explain how the project is relevant to the health care needs of Service Members, their Families, and/or Veterans.

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

Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract should be generally free of technical language/jargon and written so that individuals without a scientific or medical background can easily understand. The lay abstract is an important component of the application/proposal review process because it addresses issues of particular interest to lived experience subject matter experts (consumers).

- Clearly describe the objectives and rationale for the proposed study and intervention.
- Describe the CBPR approach and implementation in the study.
- Describe the ultimate applicability of the research and how it addresses the selected sub-area(s) ***within one of the three*** FY24 TBIPHRP CTA Focus Areas to be addressed by the proposed project and potential impact of the research (including situations/populations that would benefit).
- Describe the types of patients that will be helped by the research and how it will help them.
- Describe potential clinical applications, benefits, and risks.
- Describe the projected timeline to achieve the expected patient-related outcome.
- Describe how the proposed project will impact the health and well-being of Service Members, their Families, and/or Veterans.

- **Attachment 5: Statement of Work (seven-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

  For the FY24 TBIRPHP CTA mechanism, refer to the "Suggested SOW Strategy Clinical Research" document for guidance on preparing the SOW and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

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

  - Cross-mapping of data elements to psychological health conditions and/or TBI CDEs.
  - Including language in informed consent documents to allow for submission of de-identified data to a repository or for secondary use/meta-analysis of the data.

- FITBIR- or NIMH NDA-eligible research should also include the following subtasks:
  - Investigator and study registration within the first 30 days of the award
  - Sharing of draft data collection forms with FITBIR or NIMH NDA, as applicable
  - Annual data submission

Research Level 1 Early-Career Investigator Partnering Option: Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.

- **Attachment 6: Intervention (no page limit): Upload as "Intervention.pdf".** The intervention should include the components listed below.
  - **Description of the Intervention:** Identify the intervention to be tested and describe the particular outcomes. Describe how the intervention addresses current clinical needs and how it compares with currently available interventions and/or standards of care. As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. ***Other types of interventions (diagnostics, devices, therapies, clinical guidance, behavioral interventions) should be fully described.*** Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the clinical trial. Summarize key preclinical findings, dosage studies, and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.
  - **Study Procedures:** Describe the interaction with the human subject, including the study intervention that they will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention). Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions). Clearly delineate research procedures from routine clinical procedures. 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. Discuss how compliance with current Good Laboratory Practice (GLP) and Good Manufacturing Practices (GMP) guidelines and other regulatory considerations will be established, monitored, and maintained, as applicable.

- **Laboratory Evaluations:** State the biospecimen that will be collected along with the collection schedule and amount. Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects). Describe the specimen storage plan, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the actions to be taken to allow the use of stored specimens in future research studies, if applicable. Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **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. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.

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

- **Attachment 7: Human Subject Recruitment and Safety Procedures (no page limit): Upload as "HumSubProc.pdf".** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. ***Demonstrate that the research team has access to the proposed study population at each site and describe the efforts that will be made to achieve accrual goals.*** Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. ***For clinical trials proposing to include military personnel, refer to the General Submission Instructions, Appendix 1, for more information.***

  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Describe how the inclusion and exclusion criteria meet the needs of the proposed clinical trial. Inclusion/exclusion criteria should take into

consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

- **Inclusion Enrollment Plan:** Describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them. Address the availability of human subjects for the clinical trial for each enrollment site. If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan. Describe the recruitment and advertisement materials. Discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress.

- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects (including vulnerable populations). ***This BAA may not be used to support studies requiring an EFIC.***

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

    - Applicants must include language in informed consent documents to allow for submission of de-identified data to a repository ***(e.g., the NIMH NDA or FITBIR)*** or for secondary use/meta-analyses of the data. Provide justification if this is not possible.

    - Applicants are also strongly encouraged to include language in consent forms to allow for optional passive follow-up via electronic health record.

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

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

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

- Address how privacy and time for decision-making will be provided and whether the potential human subject will be allowed to discuss the study with anyone before making a decision.

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

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

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

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

– **Risks/Benefits Assessment:**

- **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

- **Risk management and emergency response:**

  - Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and 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. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values. Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.

- **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.

– **Data Management Plan:** Describe the data to be gathered and all methods used for collection, including the following:

- **Data:** The types of data, software, or other materials to be produced.

- **Acquisition and processing:** How the data will be acquired, including the time and location of data acquisition, if scientifically pertinent. If use of existing data resources is proposed, describe the origin of the dataset. Provide an account of the standards to be used for data and metadata format and content. Explain how the data will be processed.

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

- **Confidentiality:**

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

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

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

- **Data capture, verification, and disposition:** Describe how data will be captured and verified, including the quality assurance and quality control measures taken

during collection, analysis, and processing. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored, if applicable; the file formats and the naming conventions that will be used, the process for locking the database at study completion, and the length of time that data will be stored, along with a justification for the them frame of preservation, which may include considerations related to the balance between the relative value of data preservation and other factors such as the associated cost and administrative burden of data storage. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For Regulatory Agency oversight, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) is required.

- **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with a Regulatory Agency, if applicable.

- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study. In cases of national security or controlled unclassified information concerns, include a statement that data cannot be made available to the public (e.g., "This data cannot be cleared for public release in accordance with the requirements in DoD Directive 5230.09.").

- **Attachment 8: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Address the following and provide supporting documentation as applicable. For the FY24 TBIPHRP CTA, evidence of investigational product regulatory exemption (e.g., IND/IDE application submission, clearance or authorization has been submitted/cleared/authorized or will be submitted to the appropriate Regulatory Agency ***within the first 60 days of the award*** must be included in the application.

  – State the product/intervention name.

  For products/interventions that do not require regulation by a Regulatory Agency:

  – Provide evidence that the product/intervention does not require regulation by a Regulatory Agency. Note that this request includes but limited to software applications, algorithms, nutraceuticals, or behavioral health interventions. ***Submissions providing "not applicable," "none," or similar responses do not satisfy this request and may be administratively withdrawn.*** If the clinical trial will be conducted at international sites, provide equivalent information relevant to the host

country[ies] regulatory requirements. No further information for this attachment is required.

For products that require regulation by a Regulatory Agency:

- For investigator-sponsored investigational product regulatory exemptions (e.g., IND, IDE) provide evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the Regulatory Agency.

- State whether the product is FDA-approved, -licensed, or -cleared and marketed in the United States. State whether the product is approved, licensed, cleared and marketed outside of 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 for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

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

- For the FY24 TBIPHRP CTA ***evidence that an investigational product exemption application (e.g., IDE/IND) has been submitted/cleared/authorized has been secured or will be submitted to the appropriate Regulatory Agency within 60 days of the award must be included.*** The application should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. If an application has already been submitted to the Regulatory Agency, provide the date of submission, the application number, and a copy of the Regulatory Agency letter acknowledging the submission. Clearly identify whether a member of the study team holds the regulatory exemption (e.g., IND/IDE). If there are any existing cross-references in place, provide the investigational product regulatory exemption application (e.g., IND/IDE) number(s) and associated sponsor(s). Provide an explanation of the status of the investigational product regulatory exemption (e.g., IND/IDE) application (e.g., past the critical 30-day period, pending response to questions raised by the Regulatory Agency, on clinical hold, on partial clinical hold). Provide a summary of previous meetings with the Regulatory Agency on development of this product, if appropriate. A copy of the Regulatory Agency meeting minutes should be included if available. Provide copies of communications from the Regulatory Agency relevant to the most recent status of the investigational product regulatory exemption (e.g., IND/IDE). ***If the regulatory***

exemption application (e.g., IND/IDE) has not been submitted to the Regulatory Agency yet, indicate when the application will be submitted to the FDA, provide a timeline for obtaining the investigational product regulatory exemption within the first 60 days of award, document in the SOW (Attachment 5).

- If available, provide a copy of the communication from the Regulatory Agency indicating the investigational product regulatory exemption (e.g., IND/IDE) application is active/safe to proceed.

- If an active investigational product regulatory exemption (e.g., IND/IDE) for the investigational product is in effect but an amendment is needed to include the proposed trial, describe the type and nature of the amendment(s) ***and provide evidence of the amendment approval/clearance/authorization or amendment submission within the first 60 days of the award***. Indicate whether the amendment increases the risk of the intervention.

- If the proposed 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).

- If applicable, provide the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

- If applicable, describe the overall regulatory strategy and product development plan that will support the planned product indication or product label change. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of Regulatory Agency meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines. Identify and address the impact of intellectual property issues on product development and subsequent government access to products supported by this BAA.

- **Attachment 9: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as "Personnel.pdf".** The Study Personnel and Organization attachment should include the components listed below.

  - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person's position on the project. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate. Identify and provide justification for the inclusion of international sites, as appropriate. If

applicable, identify the Regulatory Agency sponsor and any external consultants or other experts who will assist with Regulatory Agency sponsor communications. While there is no specified format for this information, a table(s) or diagram is recommended. ***Note:*** This item may be made available for programmatic review.

- **Study Personnel Description:** Briefly describe the composition of the study team, including roles of the individuals listed in the organizational chart on the project. Study coordinator(s) and statistician should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed research. Describe relevant background and qualifications that demonstrate appropriate expertise to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, expertise in conducting clinical studies), including previous interactions with the relevant Regulatory Agency, if applicable.

- **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is cooperative (i.e., involving more than one institution), clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead institution. A single IRB is required for all institutions located in the United States that are engaged in cooperative research. 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.

- **Partnership Statement (required only for proposals/applications submitted under the Research Level 1 Early-Career Investigator Partnering Option):** Provide a statement confirming that the Early-Career Investigator meets the eligibility requirements and includes (1) the completion dates of the terminal degree and last postdoctoral/fellowship position and (2) an explanation of any lapses in research time or appointments as denoted in the biographical sketch (if applicable). ***Postdoctoral fellows are not considered independent investigators.*** 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 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. Explain how funding will be balanced between both PIs, unless otherwise warranted and clearly justified.

- **Attachment 10: Transition Plan (three-page limit): Upload as "Transition.pdf".** Research funded by the TBIPHRP should accelerate the development of tangible or knowledge products that optimize the prevention, assessment, and treatment of psychological health conditions and/or traumatic brain injuries. In the Transition Plan, Describe/discuss the methods and strategies proposed to move the research to the next phase of development or commercialization/clinical use. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the

transition plan. Applicants are encouraged to explore developing relationships with industry and/or other funding agencies in order to accelerate development. The transition plan should include the components listed below:

- Details of the overall strategy to transition to the research to commercialization or clinical use. Include a description of collaborations and other resources that will be used to provide continuity of development.
- A brief schedule and milestones for transitioning to a clinical product (even if Regulatory Agency approval/clearance is not needed). This can include the next logical step of preclinical or clinical research, next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by a Regulatory Agency.
    - For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.
        - A "knowledge product" is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, or tools or to support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities); and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
- If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.

- **Attachment 11: Impact Statement (two-page limit): Upload as "Impact.pdf".** The Impact Statement should be written in a manner that will be ***readily understood by readers without a background in science or medicine.***
    - Identify the sample population(s) that will participate in the proposed intervention, inclusive of sex, gender, and/or minorities if applicable; describe how they represent the target population that might benefit from the intervention, and describe the potential impact and anticipated outcomes of the proposed clinical trial on the lives and health of the target population with regard to the selected sub-area(s) within one of the two FY24 TBIPHRP CTA Focus Areas.
    - Describe the anticipated short-term (immediate to 5 years) and long-term (greater than 5 years) impact of the proposed work on improved patient care and/or quality of life.

- Describe any potential issues that might limit the impact of the proposed research and provide approaches to overcome.

- **Attachment 12: 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, their Families, and/or Veterans.

  - 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 DOD Instruction 6200.02, the DOD 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 DOD 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 13: CBPR Documentation (no-page limit): Start each document 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, 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 14: Representations *(if applicable)*: Upload as "RequiredReps.pdf".** All applicants must complete and submit the Required Representations template available

on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Submission Instructions, Appendix 5, Section B, Representations.

- **Attachment 15: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form" available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs.

(c) Research & Related Personal Data: Refer to the General Submission Instructions, Section IV.B.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): Refer to the General Submission Instructions, Section IV.B.(d), for detailed instructions.

- **PI Biographical Sketch (six-page limit):** Upload as "Biosketch_LastName.pdf".
- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
  - Key Personnel Biographical Sketches (six-page limit each): Upload as "Biosketch_LastName.pdf".
  - CBPR: Biographical sketches, or an equivalent document, should also be included for CBPR team member(s) to demonstrate background and experience relevant to their role in the proposed research project.
- **Key Personnel Biographical Sketches (six-page limit each):** Upload as "Biosketch_LastName.pdf".
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

(e) Research & Related Budget: Refer to the General Submission Instructions, Section IV.B.(e), for detailed instructions.

- **Budget Justification (no page limit):** Refer to General Submission Instructions, Section IV.B.(e), Budget Justification Instructions.
- ***Early-Career Investigator Partnering Option:*** Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for the Partnering PI

even if they are located within the same organization. Refer to Section II.D.6, Funding Restrictions, for detailed information.

(f) Project/Performance Site Location(s) Form: Refer to the General Submission Instructions, Section IV.B.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable)*: Refer to the General Submission Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 15.

II.D.2.b.iii. Full Application Submission Components for the Partnering PI

The application submission process for the Partnering PI uses an abbreviated full application/proposal package. Refer to the equivalent attachment above for details specific to each of the following application components.

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

(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: Upload as "RequiredReps.pdf".**
- **Attachment 15: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as "IGBudget.pdf".**

(c) Research & Related Personal Data: Refer to the General Submission Instructions, Section IV.B.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): Refer to the General Submission Instructions, Section IV.B.(d), for detailed instructions for detailed information.

- PI Biographical Sketch (six-page limit): Upload as "Biosketch_LastName.pdf".
- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".
  - Key Personnel Biographical Sketches (six-page limit each): Upload as "Biosketch_LastName.pdf".

- CBPR: Biographical sketches, or an equivalent document, should also be included for CBPR team member(s) to demonstrate background and experience relevant to their role in the proposed research project.

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

(e) Research & Related Budget: Refer to the General Submission Instructions, Section IV.B.(e), for detailed instructions.

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

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for the Partnering PI even if they are located within the same organization. Refer to Section II.D.6, Funding Restrictions, for detailed information.

(f) Project/Performance Site Location(s) Form: Refer to the General Submission Instructions, Section IV.B.(f), for detailed information.

(g) Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Submission Instructions, Section IV.B.(g), for detailed information.

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

- **Intramural DOD Collaborator(s):** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 15

II.D.2.c. Verification of Full Application/Proposal Submission in eBRAP

Once the full application/proposal is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application/proposal submission. Verification is strongly recommended but not required. eBRAP will validate full application/proposal files against the specific BAA requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's/offeror's responsibility to review all application/proposal components and ensure proper ordering as specified in the BAA. ***The Project Narrative and Research & Related Budget Form cannot be changed after the full application/proposal submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application/proposal package must be submitted prior to the full application/proposal submission deadline.*** Other application/proposal components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the submission verification period. The full application/proposal cannot be modified once the submission verification period ends.

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

The applicant/offeror organization must be registered as an entity in SAM (https://www.sam.gov/content/home) and receive confirmation of an "Active" status before submitting an application/proposal through Grants.gov. Organizations must include the UEI generated by SAM in submission to this funding opportunity.

II.D.4. Submission Dates and Times

The pre-application/proposal and full application/proposal submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

II.D.5. Intergovernmental Review

Not applicable

II.D.6. Funding Restrictions

For Research Level 1

- The maximum period of performance is **3** years.
- The application/proposal's direct costs budgeted for the entire period of performance should not exceed **$500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. 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 **3** years.

For Research Level 1 Early-Career Investigator Partnering Option

- The maximum period of performance is **3** years.
- The **combined direct costs** budgeted for the entire period of performance for the Initiating PI and Partnering PI proposals/applications will not exceed **$500,000.** The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified. 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 **3** years.

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

For Research Level 2

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

- The application/proposal's direct costs budgeted for the entire period of performance should not exceed **$2.0M**. 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.

For Research Level 3

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

- The application/proposal's direct costs budgeted for the entire period of performance should not exceed **$4.0M**. 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.

For all application/proposals:

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

- **Single PI:** In years three and four, travel costs for the PI to present project information or disseminate project results at a DOD-sponsored meeting (e.g., Interim/In-Progress Review [IPR] meeting or Military Health System Research Symposium). For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area.

- **Early-Career Investigator Partnering Option:** In years three and four, travel costs for the Initiating and Partnering PIs to present project information or disseminate project results at a DOD-sponsored meeting (e.g., Interim/In-Progress Review [IPR] meeting or Military Health System Research Symposium). For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area.

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

- Travel costs in support of multidisciplinary collaborations.
- Starting in year two, travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 TBIPHRP CTA.
- Early-Career Investigator Partnering Option: Starting in year 2, travel costs for the Initiating and Partnering PIs to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 TBIPHRP CTA.
- Costs associated with CBPR implementation.
- 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):
    - Considerations
        - 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.
    - Curation and developing supporting documentation, including formatting according to accepted community standards; de-identification; preparing metadata to foster discoverability, interpretation, and reuse; and formatting for transmission to and storage at a selected repository for long-term preservation and access.
    - Local management considerations, such as unique and specialized information infrastructure necessary to provide local management and preservation (e.g., before deposit into an established repository).

- Preserving and sharing through established repositories, such as data deposit fees necessary for making data available and accessible. For example, if a Data Management and Sharing Plan proposes preserving and sharing scientific data for 3 years in an established repository with a deposition fee, the cost for the entire 3-year period must be paid prior to the end of the period of performance. If the Plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

II.D.7. Other Submission Requirements

Refer to the General Submission Instructions, Appendix 2, for detailed formatting guidelines.

II.E. Application/Proposal Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications/proposals will be individually evaluated according to the following **scored criteria**, of which **Research Strategy and Feasibility, Human Subject Recruitment,** and **Intervention** are equally of most importance and the remaining criteria listed are of equal importance:

- **Research Strategy and Feasibility**
  - How well the scientific rationale, literature review, unpublished data, preliminary studies, and/or preclinical data support the development of the proposed clinical trial research project, provide the basis for the study questions and/or hypotheses, and justify the research level requested.
  - To what extent the research project is feasible and will be completed within the proposed period of performance.
  - How well the proposed clinical trial is described and designed with the appropriate primary, secondary, or interim endpoints/outcome measures.
  - How well the application/proposal acknowledges potential problem areas and discusses alternative methods/approaches that may be employed to overcome them.
  - How well the inclusion/exclusion criteria and group assignment process meet the needs of the proposed clinical trial.
  - To what degree the data collection instruments are appropriate to the proposed study.
- **Human Subject Recruitment**
  - How well the application addresses the availability of human subjects for the clinical trial and the prospect of their participation.

- Whether the application/proposal demonstrates access to the proposed study population at each site.

- The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial.

- How well the application/proposal identifies any potential barriers to accrual and provides mitigation plans for addressing unanticipated delays (e.g., slow accrual, attrition).

- If applicable, how well the inclusion of international sites is justified.

- Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

- **Intervention**

  - How the intervention compares with currently available interventions and/or standards of care.

  - If applicable, whether there is evidence indicating availability of the intervention from its source for the duration of the proposed clinical trial (if applicable).

  - To what degree the intervention addresses the clinical need described.

  - To what degree the application includes key preclinical findings, dosage studies, and/or other clinical evidence (if applicable) to support the safety and stability (as appropriate) of the intervention.

  - How well research procedures are clearly delineated from routine clinical procedures.

  - Whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).

- **Regulatory Strategy and Transition Plan**

  - If applicable, whether evidence that the product/intervention does not require regulation by a Regulated Agency is provided and reasonable.

  - If applicable, how the overall regulatory strategy and product development plan that will support the planned product indication or product label change.

  - As appropriate, whether the application/proposal includes evidence that the IND or IDE application (or international equivalent) has submitted/cleared/authorized or will be submitted to the appropriate Regulatory Agency within the first 60 days of the award.

- For investigator-sponsored investigational product regulatory exemptions (e.g., IND, IDE), whether there is evidence of appropriate institutional support.
- Whether plans to comply with current GLP, GMP, and GCP guidelines are appropriate.
- Whether a member of the study team is the regulatory sponsor and holds the investigational product regulatory exemption (e.g., IND/IDE) for the proposed indication.
- Whether the overall strategy described to transition the research to commercialization or clinical use is reasonable and achievable.
- Whether the schedule and milestones for transitioning the research to a clinical product are achievable.
- Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
- How well the application/proposal identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization.
- If applicable, how well the application/proposal describes an appropriate intellectual and material property plan among participating organizations.
- If applicable, how well the application/proposal addresses any impact of intellectual property issues on product development and the government's ability to access such products or technologies in the future.

- **Impact**
  - How impactful the anticipated outcomes of the proposed clinical trial would be to the target population with regard to at least one sub-area within one of the two FY24 TBIPHRP CTA Focus Areas.
  - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
  - To what extent the proposed clinical trial will provide short- and long-term impact on patient care and/or quality of life for individuals
  - How well the application acknowledges potential issues that might limit impact and provides approaches to overcome.
- **Ethical Considerations**
  - How the level of risk to human subjects is minimized and how the safety monitoring and reporting is appropriate for the level of risk.
  - To what degree privacy and confidentiality of study records are appropriately considered.

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

- **Statistical Plan and Data Analysis**
  - How the statistical plan, including sample size projections and power analysis, is appropriate to meet the objectives of the study and all proposed correlative studies.
  - If applicable, whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.
  - If applicable, whether the plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity for phase 3 clinical trials are appropriate for the proposed research.

- **Personnel and Communication**
  - Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
  - To what degree the study team's background and experience/expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, expertise in conducting clinical studies).
  - How the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
  - How well the study management plan (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.
  - For clinical trials that involve more than one institution, to what degree the multi-institutional structure governing the research protocol(s) across all participating institutions and regulatory submission plan are described and appropriate.

- **Partnership (only applicable to Research Level 1 Early-Career Investigator Partnering Option proposals/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.
  - To what degree the partnership will better address the research question together rather than through separate individual efforts.
  - 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.

- Whether funding will be balanced between both PIs or is otherwise warranted and clearly justified.

- **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.

- **Data and Research Resources Sharing Plan**

  - To what extent the data and resources generated during the performance of the project will be shared with the research community, including the sharing of de-identified data with data repositories.

  - For studies with prospective human subject enrollment, how thoroughly the application incorporates CDEs appropriate to each field of study.

  - For studies with prospective human subject enrollment, how well the application justifies any instances where existing CDEs are not applicable or appropriate (if applicable).

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

- **Environment**

  - To what degree the scientific environment, clinical setting, and accessibility of institutional resources support the proposed clinical trial at each participating center or institution (including collaborative arrangements).

  - Whether there is evidence for appropriate institutional commitment from each participating institution.

- **Budget**
    - Whether the **direct** costs exceed the allowable direct costs as published in the BAA.
    - Whether the budget is appropriate for the proposed research.
    - If applicable, whether funding will be balanced between both PIs or is otherwise warranted and appropriately justified.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application/proposal components influence the review.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s)/proposal(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the DHP and FY24 TBIPHRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Relative impact
    - Relevance to military health

II.E.2. Application/Proposal Review and Selection Process

All applications/proposals are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications/proposals against established criteria to determine technical merit, where each application/proposal is assessed for its own merit, independent of other applications/proposals. The second tier is **programmatic review**, a comparison-based process in which applications/proposals with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications/proposals from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of

confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant/offeror or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application/proposal. Violations by panel members or applicants/offerors that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an 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/offeror that is available in SAM.

An applicant/offeror organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant/offeror, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's/offeror's integrity, business ethics, and record of performance under federal awards when determining an awardee's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each organizational representative and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application/proposal and an information paper describing the funding recommendation 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.

If an application/proposal 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 awardee organization.

Only an appointed USAMRAA Warranted Official 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 USAMRAA Warranted Official is the official authorizing document (i.e., assistance agreement).***

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

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

For assistance agreement awards, an organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award.

For contract awards, an organization may request and negotiate pre-contract costs prior to contract award.

Refer to the General Submission Instructions, Section IV.B.(e), Pre-Award Costs section, for additional information about pre-award costs.

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

II.F.2. PI Changes and Award Transfers

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

The organizational transfer is strongly discouraged and, in most cases, will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the USAMRAA Warranted Official.

Refer to the General Submission Instructions, Appendix 7, Section F, for general information on organization or PI changes.

II.F.3. 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 BAA.

Applicable requirements in the FAR, found in 48 CFR, Chapter 1; and DFARS, found in 48 CFR, Chapter 2, apply to contracts resulting from this BAA. Refer to additional FAR and DFARS clauses as outlined in Appendix 3.

Refer to the General Submission Instructions, Appendix 7, for general information regarding administrative requirements.

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

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

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

II.F.4. Reporting

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

If the award made under this funding opportunity announcement is a contract, additional reporting requirements may apply.

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

Awards resulting from this BAA may entail additional reporting requirements related to awardee integrity and performance matters. Awardee organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These awardees are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Submission Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding BAA content or submission requirements as well as technical assistance related to pre-application/proposal submission

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

II.H. Other Information

II.H.1. Administrative Actions

After receipt of full applications/proposals, the following administrative actions may occur.

II.H.1.a. Rejection

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

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

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

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Intervention (Attachment 6) is missing.
- Human Subject Recruitment and Safety Procedures (Attachment 7) is missing.
- Regulatory Strategy (Attachment 8) is missing.
- Study Personnel and Organization (Attachment 9) is missing.
- Transition Plan (Attachment 10) is missing.
- Impact Statement (Attachment 11) is missing.
- Relevance to Military Health Statement (Attachment 12) is missing.
- CBPR Documentation (Attachment 13) is missing.

II.H.1.b. Modification

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

II.H.1.c. Withdrawal

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

- An FY24 TBIPHRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application/proposal or full application/proposal processes including, but not limited to, concept design, application/proposal development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. ***A list of the FY24 TBIPHRP Programmatic Panel members can be found at https://cdmrp.health.mil/tbiphrp/panels/panels24***.
- The application/proposal fails to conform to this BAA description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications/proposals that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).
- Personnel from applicant/offeror or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications/proposals from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications/proposals submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application/proposal includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Applications/proposals submitted by an intramural DOD organization as the contracting organization.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- The application/proposal consists solely or primarily of planning, engineering, manufacturing, or formulation activities.
- The invited application/proposal proposes a different research project than that described in the pre-proposal/pre-application.
- The proposed research is not a clinical trial.
- A clinical trial is proposed that requires an EFIC.
- The PI(s) or Early-Career Investigator do not meet the eligibility criteria.
- **Early-Career Investigator Partnering Option:** Failure to submit both (Initiating and Partnering PI) proposals/applications by the deadline.
- The application/proposal does not include a CBPR approach.
- Application failed to address at least one sub-area within one of the two FY24 TBIPHRP CTA Focus Areas.
- Evidence is not provided that the investigational product regulatory exemption (e.g., IND/IDE) application was submitted or authorized without clinical hold status.
- Evidence is not provided that the investigational product regulatory exemption (e.g., IND/IDE) application has been submitted/authorized/cleared or will be submitted in the first 60 days of the award.
- The application/proposal does not demonstrate support for and access to relevant population(s) and/or resources(s).

II.H.1.d. Withhold

Applications/Proposals that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Warranted Official for a determination of the final disposition of the application/proposal.

II.H.2. Full Application/Proposal Submission Checklist

Full Application Components	Uploaded	
	Single or Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance *(Extramural 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"	☐	☐
Intervention – Attachment 6, upload as "Intervention.pdf"	☐	
Human Subject Recruitment and Safety Procedures (*if applicable*) – Attachment 7, upload as "HumSubProc.pdf"	☐	
Regulatory Strategy – Attachment 8, upload as "Regulatory.pdf"	☐	
Study Personnel and Organization – Attachment 9, upload as "Personnel.pdf"	☐	
Transition Plan – Attachment 10, upload as "Transition.pdf"	☐	
Impact Statement – Attachment 11, upload as "Impact.pdf"	☐	
Relevance to Military Health Statement – Attachment 12, upload as "military.pdf"	☐	
CBPR Document – Attachment 13, upload as "CBPR.pdf"	☐	
Representations *(if applicable)* – Attachment 14, upload as "RequiredReps.pdf".		
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 15, upload as "IGBudget.pdf".	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐	☐

Full Application Components	Uploaded	
	Single or Initiating PI	Partnering PI
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐	☐
Budget *(Intramural submissions only)* Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form (*if applicable)*	☐	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ASR	Acute Stress Reaction
BAA	Broad Agency Announcement
CAB	Community Advisory Board
CBPR	Community-Based Participatory Research
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
CPG	Clinical Practice Guideline
CTA	Clinical Trial Award
DFARS	Defense Federal Acquisition Regulation Supplement
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EFIC	Exception from Informed Consent
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FFRDC	Federally Funded Research and Development Center
FITBIR	Federal Interagency Traumatic Brain Injury Research
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IDE	Investigational Device Exemption
IND	Investigational New Drug
IPR	Interim/In-Progress Review
IRB	Institutional Review Board
LAR	Legally Authorized Representative
LEC	Lived Experience Consultant
M	Million

MIPR	Military Interdepartmental Purchase Request
NDA	NIMH Data Archive
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
PI	Principal Investigator
PTSD	Posttraumatic Stress Disorder
SAM	System for Award Management
SOW	Statement of Work
TBI	Traumatic Brain Injury
TBIPHRP	Traumatic Brain Injury and Psychological Health Research Program
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs

APPENDIX 2: DOD and VA WEBSITES

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

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

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

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

Combat Casualty Care Research Program
https://cccrp.health.mil/Pages/default.aspx

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

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

Defense Health Agency
https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/

Defense Suicide Prevention Office
https://www.dspo.mil/

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

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

Military Health System Research Symposium
https://mhsrs.health.mil/sitepages/home.aspx

Military Infectious Diseases Research Program
https://midrp.health.mil/

Military Operational Medicine Research Program
https://momrp.health.mil/

Navy Bureau of Medicine and Surgery
https://www.med.navy.mil/

Naval Health Research Center
https://www.med.navy.mil/Naval-Medical-Research-Command/R-D-Commands/Naval-Health-Research-Center/

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/Navy-and-Marine-Corps-Force-Health-Protection-Command/

Naval Medical Research Command
https://www.med.navy.mil/Naval-Medical-Research-Command/

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

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

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

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

U.S. Army Aeromedical Research Laboratory
https://usaarl.health.mil/

U.S. Army Combat Capabilities Development Command
https://www.army.mil/devcom

U.S. Army Institute of Surgical Research
https://usaisr.health.mil/

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

U.S. Army Medical Research and Development Command
https://mrdc.health.mil/

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

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

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

U.S. Army Sharp, Ready and Resilient Directorate
https://www.armyresilience.army.mil/sharp/index.html

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

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

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

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

APPENDIX 3: FAR & DFARS CLAUSES APPLICABLE TO CONTRACTS REQUIREMENTS

FAR/DFARS Provisions/Clauses: For purposes of illustration, the following provisions and clauses may be applicable to procurement contracts resulting from this BAA. Additional clauses apply based upon contract type. The USAMRAA reserves the right to include all relevant and current FAR or DFARS clauses in the final contract award.

# Provision	Clause
52.204-7	System for Award Management
52.204-13	System for Award Management Maintenance
52.204-16	Commercial and Government Entity Code Reporting
52.204-21	Basic Safeguarding of Covered Contractor Information Systems
52.204-24	Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
52.204-26	Covered Telecommunications Equipment or Services-Representation
52.204-27	Prohibition on ByteDance Covered Application
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters
52.215-20	Requirements for Certified Cost and Pricing Data and Data Other than Certified Cost and Pricing Data
52.215-16	Facilities Capital Cost of Money
52.215-22	Limitations on Pass Through Charges - Identification of Subcontract Effort
52.216-1	Type of Contract
52.216-27	Single or Multiple Awards
52.217-4	Evaluation of Options Exercised at time of Contract Award
52.217-5	Evaluation of Options
52.217-9	Option to Extend the Term of the Contract
52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation (Applies if Exceeds $10M)
52.222-50	Combating Trafficking in Persons
52.222-56	Certification Regarding Trafficking in Persons Compliance Plan
52.223-6	Drug Free Work Place
52.226-2	Historically Black College or University and Minority Institution Representation
52.230-7	Proposal Disclosure - Cost Accounting Practice Changes
52.232-15	Progress Payments Not Included
52.233-2	Service of Protest
52.252-1	Solicitation Provisions Incorporated by Reference
52.252-3	Alterations in Solicitation
52.252-5	Authorized Deviations in Provisions
252.203-7002	Requirement to Inform Employees of Whistleblower Right
252.203-7005	Representation Relating to Compensation of Former DoD Officials
252.204-7007	Alternate A, Annual Representations and Certifications

# Provision	Clause
252.204-7008	Compliance with Safeguarding Covered Defense Information Controls
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting
252.204-7018	Prohibition on the Acquisition of Covered Defense Telecommunications Equipment or Services
252.215-7003	Requirements for Submission of Data Other than Certified Cost or Pricing Data - Canadian Commercial Corporation
252.204-7000	Disclosure of Information
252.235-7010	Acknowledgement of Support and Disclaimer
252.235-7011	Final Scientific or Technical Report
252.204-7019	Notice of NIST SP 800-171 DoD Assessment Requirements
252.204-7020	NIST SP 800-171 DoD Assessment Requirements
252.219-7000	Advancing Small Business Growth
252.225-7048	Export Controlled Items
252.225-7055	Representation Regarding Business Operations with the Maduro Regime
252.225-7057	Preaward Disclosure of Employment of Individuals Who Work in the People's Republic of China
252.225-7058	Postaward Disclosure of Employment of Individuals Who Work in the People's Republic of China
252.225-7059	Prohibition on Certain Procurements from the Xinjiang Uyghur Autonomous Region–Representation
252.225-7060	Prohibition on Certain Procurements from the Xinjiang Uyghur Autonomous Region
252.225-7966	Prohibition Regarding Russian Fossil Fuel Business Operations—Representation
252.225-7967	Prohibition Regarding Russian Fossil Fuel Business Operations

APPENDIX 4: ADDITIONAL FOCUS AREA INFORMATION

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

Psychedelic clinical trials involving eligible Service Members are allowed: Section 723 of the National Defense Authorization Act for Fiscal Year 2024 authorizes the DOD to conduct research involving using psychedelic substances (e.g., 3,4-Methylenedioxy-methamphetamine, psilocybin, ibogaine, 5-Methoxy-N,N-dimethyltryptamine, and other plant-based alternative therapies) as treatments for TBI or posttraumatic stress disorder (PTSD). The Secretary of the DOD may authorize any member of the Armed Forces serving on active duty who is diagnosed with a covered condition (TBI or PTSD) to participate in a clinical trial. ***Submissions including a clinical trial involving psychedelic interventions and Service Members are allowed and will openly compete with other research submissions during the application review and selection process.*** *Such trials recommended for funding may be subject to additional review and approval processes.*

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.

        - *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), and psychological health issues are within scope.

- *Optimized messaging for successful dissemination and implementation.*
- *Inclusion of families1 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.

- *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[5] to improve 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 during the 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.*

[5] Intervention repurposing is the identification of novel indication(s) for an FDA-approved intervention.

- *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.

c. Health services research to improve provider adoption of evidence-based practices, improve access, and reduce barriers. In addition, factors that influence treatment engagement, follow-up care, and improvement of long-term outcomes are of interest.

    - *Research of interest includes, but 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 interventions.*