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: HT9425-23-S-TBIPH1

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Proposal/Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 15, 2023
- **Invitation to Submit a Proposal/Application:** July 27, 2023
- **Proposal/Application Submission Deadline:** 11:59 p.m. ET, September 28, 2023
- **End of Proposal/Application Verification Period:** 5:00 p.m. ET, October 3, 2023
- **Peer Review:** December 2023
- **Programmatic Review:** February 2024

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

TABLE OF CONTENTS

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

Proposal/application submission by extramural organizations through Grants.gov requires use of the Workspace interface, which separates the proposal/application package into individual forms. Applicants must create a Workspace in Grants.gov, complete the required forms, and submit their proposal/application Workspace package.

This Funding Opportunity Announcement is a Broad Agency Announcement (BAA) through the Fiscal Year 2023 (FY23) 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 FY23 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 FY23 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 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

Proposals/applications to the FY23 TBIPHRP CTA are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by 10 USC 4001. The execution management agent for this BAA is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC).

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 FY22 totaled $2.222 billion. The FY23 appropriation is $175 million (M).

The TBIPHRP's vision is to optimize the prevention, assessment, and treatment of psychological health conditions and/or TBIs. ***Proposed research can be aligned with TBI, psychological health, or both.*** The program seeks to fund research that accelerates solutions to improve the health, well-being, and health care of Service Members, their Families, Veterans, military beneficiaries, and the American public. ***Proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.***

II.A.1. FY23 TBIPHRP 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 three FY23 TBIPHRP CTA Focus Areas listed below. Bulleted items are provided to indicate additional context regarding programmatic intent but not required to be specifically addressed by applications. ***Proposed research must be hypothesis driven and can be aligned with TBI, psychological health, or both.*** Proposals/applications consisting solely or primarily of planning, engineering, manufacturing, or formulation activities may be administratively withdrawn. Selection of the appropriate FY23 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.

1. **Understand:** Research will address knowledge gaps in, epidemiology, and etiology of psychological health conditions and/or TBI.

    a. Understanding sexual harassment and assault prevention, perpetration, victimization, and response. Methodologies that ensure anonymity for participants are strongly encouraged. Research of interest includes, but is not limited to:

        - Understanding processes of shame, stigma, and institutional betrayal among sexual assault victims and their units/teams and evaluation of approaches to mitigate these experiences. Experiences of marginalized groups, male victims, and victims of intimate partner and family[1] violence are of particular interest.

        - Understanding how interpersonal and individual conditions, choices, behaviors, and psychological health are influenced by organizational-level factors relate to sexual assault and harassment prevention, perpetration, and response. Measurement and analysis of organizational-level factors, such as culture, climate, and training, beyond aggregating individual perceptions, are encouraged. Research could include the progression from sexual harassment to sexual assault and factors influencing sexual harassment.

[1] Within the context of the FY23 TBIPHRP CTA Focus Areas, "family" should be broadly defined to include not just spouses, but also parents, significant others/fiancés/partners, children, caregivers, or close friends.

- Understanding barriers to reporting sexual assault and factors that contribute to retaliation within units/teams and evaluation of approaches to mitigate barriers, prevent retaliation, and improve psychological health outcomes of victims. Research could include data from influencers, bystanders, and perpetrators, as well as environmental, structural, and demographic factors (e.g., workplace culture, climate, senior leader diversity, age, gender).

2. **Prevent and Assess:** Research will address the prevention or progression of psychological health conditions and/or TBI conditions through population, selective, and indicated prevention approaches. Efforts that focus on primary prevention (including protection), screening, diagnosis, and prognosis are within scope.

   a. Identification and validation of biomarkers or other objective markers for diagnosis, prognosis, or monitoring of psychological health conditions and/or TBI, repetitive exposures, and associated sequelae (e.g., chronic migraine, dizziness, neurocognitive symptoms, sleep, post-traumatic headache, secondary complications).

   b. Approaches or tools to prevent or reduce risk of psychological health conditions and/or TBI. Research of interest includes, but is not limited to:

      - 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 of injury thresholds and exposure standards for TBI.

   d. Development, evaluation, and implementation of crosscutting prevention approaches targeting upstream factors or leveraging communities and peers to address multiple adverse outcomes such as suicide, multiple forms of violence, and alcohol and substance use disorders. Examples of upstream factors could include social connectedness, inclusiveness, culture, problem-solving, emotional regulation, communication, underlying health disparities, financial stability, geographical isolation, rural challenges, and environmental extremes. Research of interest may include, but is not limited to:

      - Optimized messaging for successful dissemination and implementation.

- Inclusion of families and evaluation of family impact.

- Culturally acceptable approaches to reducing access to lethal means and promoting means safety for suicide and violence prevention.

e. Development of solutions to increase readiness and psychological resilience in individuals, small teams, families, and communities to ameliorate the potential negative impacts of specific military and life stressors. Research of interest includes, but is not limited to:

- Effective pharmacologic or non-pharmacologic prevention interventions. Solutions for prevention of acute stress reactions (ASRs) and posttraumatic stress disorder (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.

f. Development of solutions to address aspects of workplace culture and climate (e.g., leadership attitudes, group characteristics, group identification factors) that are associated with increases in harmful behaviors. Research of interest includes, but is not limited to, solutions to provide and incentivize positive options and substitutes for alcohol and substance use and promote pro-social behavioral norms.

3. **Treat:** Research will address immediate and long-term treatments and improvements in systems of care, including access to and delivery of health care services. Treatment topics may include novel treatments and interventions, personalized medicine approaches, length and durability of treatment, rehabilitation, relapse, and relapse prevention.

a. Interventions that promote sustained functional recovery, including interventions administered acutely, during the post-acute phase, or during the chronic phase of injury. Research of interest includes, but is not limited to:

- Rapid assessments and treatments for psychological health conditions. Interventions addressing adjustment disorders, ASRs, and PTSD may be proposed.

- Mobile health technologies to improve mental health and well-being.

- Interventions focused on sensory and motor dysfunction after brain injury.

- Interventions that address neurodegenerative processes associated with TBI.

- Interventions that restore cognitive reserve and functioning.

- Novel therapeutic candidates based on evolving changes of pathophysiology and/or theoretical mechanisms of psychological health conditions and/or TBI.

- Interventions and/or the delivery of health care services to improve the ability to treat co-occurring TBI and psychological health conditions.

- Personalized medicine approaches to treatment that may include tailoring treatment to the biological and endophenotypic elements present. Treatment approaches may consider how TBI, PTSD, depression, or other psychological health conditions are interrelated.

- Considerations for sequencing and optimal combinations of pharmacologic and non-pharmacologic interventions.

- Effective, early interventions for delivery in rural or other resource-limited environments (e.g., far-forward military environments), and/or by non-clinicians (e.g., peers, teams, first responders/medics).

b. Validated methods for reducing barriers to care for psychological health conditions and/or TBI challenges (e.g., PTSD, suicidal ideation or behaviors, alcohol and substance use, anxiety, depression) and informing processes that lead to increases in help-seeking behavior.

    - Research of interest includes, but not limited to, individual, peer/unit/team, leader, family, caregivers, community, and enterprise-level methods.

c. Implementation, follow-up, and services research to increase provider adoption and availability of evidence-based treatments, as well as treatment engagement, follow-up care, and understanding of long-term outcomes. Research of interest includes, but is not limited to:

    - Clinical effectiveness studies comparing new/novel capabilities to existing evidence-based treatments and/or the standard of care.

    - Identification and evaluation of methods for successful dissemination and implementation of interventions.

d. Effective postvention strategies to address social connectedness during reintegration of individuals into workplace or community environments following a sexual assault, suicide event, or other severe trauma. Proposed research should also consider preventing subsequent suicides or other counterproductive behaviors among individuals and community members.

II.A.2. Award History

The TBIPHRP CTA was first offered in FY21. Since then, 180 CTA proposal/applications have been received, and 27 have been recommended for funding.

II.B. Award Information

The intent of the FY23 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 both.***

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 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 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. For more information, see the Human Subject Resource Document. Principal Investigators (PIs) proposing comparative effectiveness, implementation science, health care services research as the primary research objective should consider the ***FY23 TBIPHRP Health Services Research Award (Funding Opportunity Number HT9425-23-TBIPHRP-HSRA).*** PIs seeking funding for a preclinical research project should consider one of the other FY23 TBIPHRP program announcements or the FY23 Focused Program Award BAA being offered.

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

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

Key aspects of the FY23 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 proposal/application **must** include Community-Based Participatory Research (CBPR) approaches in the development and execution of the clinical trial. CBPR approaches should be documented in Attachments 12 and 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 proposal/application should demonstrate the documented availability of and access to the drug/compound, device, and/or other materials needed, as appropriate, for the proposed duration of the study.

- **Personnel and Environment:** The proposal/application 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 proposal/application 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 proposal/application should show strong institutional support and, if applicable, a commitment to serve as the regulatory sponsor, ensuring all sponsor responsibilities described in the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312), Subpart D, for 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 bio-equivalence, 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 proposal/application should include a clearly articulated statistical analysis plan, a power analysis reflecting sample size projections that will answer the objectives of the study, and a data management plan 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.

If the proposed clinical trial involves the use of drug that has not been approved by a Regulatory Agency for the proposed investigational use, then an Investigational New Drug (IND) application to the FDA that meets all requirements under 21 CFR 312 or international equivalent application may be required.

- It is the responsibility of the applicant to provide evidence from the IRB of record or Regulatory Agency if an investigational drug (e.g., IND) application is not required. ***If an investigational drug application is required, evidence that an application (e.g., IND) has been submitted, cleared, or authorized without clinical hold status must be included in the FY23 TBIPHRP CTA proposal/application.***

- The investigational drug application should be specific for the product (i.e., the product should not represent a derivative or alternate version of the investigational agent described in the investigational drug application) and indication to be tested in the proposed clinical trial.

If the proposed clinical trial involves the use of device that has not been approved by a Regulatory Agency for the proposed investigational use, then an Investigational Device Exemption (IDE) application to the FDA that meets all requirements under 21 CFR 812 or international equivalent may be required.

- It is the responsibility of the applicant to provide evidence if an investigational device (e.g., IDE) application is not required or the device qualifies for an abbreviated IDE or (equivalent international application). ***If an investigational device application is required, evidence that an application (e.g., IDE) has been submitted, cleared, or authorized without clinical hold status has been secured must be included in the FY23 TBIPHRP CTA proposal/application***.

- The application should be specific for the device (i.e., should not represent a derivative or modified version of the device described in the investigational device application) and indication to be tested in the proposed clinical trial.

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 submitted or approved must be included in the FY23 TBIPHRP CTA proposal/ application*** within Attachment 8, Regulatory Strategy.

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

Research Scope: 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. ***This BAA may not be used to support studies requiring an exception from informed consent (EFIC).*** Selection of the appropriate FY23 TBIPHRP CTA Research Level is the responsibility of the applicant:

- **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 proposal/application's ***direct*** costs budgeted for the entire period of performance should not exceed **$500,000**.

    - **Early-Career Investigator Partnering Option:** The FY23 TBIPHRP encourages proposals/applications that include meaningful and productive collaborations between investigators. The FY23 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 proposal/application. One PI will be identified as the Initiating PI and will be responsible for most of the administrative tasks associated with proposal/application submission. The other investigator will be the Partnering PI. ***One of the named PIs on a proposal/application submitted under the Early-Career Investigator Partnering Option must be an Early-Career Investigator who may be either the Initiating or Partnering PI***.

- 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 proposal/application 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 proposal/application is critical for the research strategy and completion of the SOW, and why the work should be done together rather than through separate efforts.

- If recommended for funding, each PI will be named to an individual award within the recipient organization. For individual DOD FY23 TBIPHRP submission requirements for the Initiating and Partnering PI, refer to Section II.D.2, Content and Form of the Proposal/Application 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 proposal/application'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 proposal/application's ***direct costs*** budgeted for the entire period of performance should not exceed **$4.0M**.

Funded studies are required to register the study in the NIH clinical trials registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Submission Instructions, Appendix 1, Section B, for further details.

Refer to Section II.D.6, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2024. For additional information refer to Section II.F.1, Federal Award Notices.

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

- Collaboration with DOD or VA investigators or consultants

Collaborations between researchers at military or Veterans institutions and non-military institutions 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 II.

Use of DOD or VA Resources: If the proposed research involves access to VA or DOD patient populations, resources, or databases, the proposal/application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to Section II.D.2.b.ii, Full Proposal/Application Submission Components, 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.***

Access to certain DOD or VA patient populations, resources, or databases may only be obtained by collaboration with a DOD or VA investigator who has a substantial role in the research and may not be available to a non-DOD or non-VA investigator if the resource is restricted to DOD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DOD or non-VA investigator collaborating with the DOD and/or VA.

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.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and

approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of proposal/application submission is ***not*** required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of ***all required and complete*** documents to the OHRO. Refer to the General Submission Instructions, Appendix 1, and the OHRO web page (https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo) for additional information.

Multi-Institutional Clinical Trials: As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research ***must*** rely on a single IRB to review and approve the portion of the research conducted at domestic sites (45 CFR 46.114(b)). If the proposed, non-exempt research involves more than one U.S.-based institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Communication and data transfer between or among the collaborating institutions, as well as how specimens and/or imaging products obtained during the study will be handled, should be included in the appropriate sections of the application. A separate intellectual and material property plan agreed on by all participating institutions is also required for multi-institutional clinical trials.

Optimizing Research Impact Through Community Collaboration: Research funded by the FY23 TBIPHRP should be responsive to the psychological health conditions and/or TBI needs of the lived experience, 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 FY23 TBIPHRP CTA, inclusion of CBPR approaches is required*** and should be documented in Attachment 12, CBPR Letters of Commitment, and Attachment 13, CBPR Statement.

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 Lived Experience Consultation (LEC), can also have important impacts on translational research and prototype development to identify and augment the potential impact of a research program 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. ***CBPR team members cannot be employees of any of the organizations participating in the proposal/application.*** Some examples of CBPR collaborations include:

- LEC: The research team includes at least one member with lived psychological health conditions and/or TBI experience who will provide advice and consultation throughout the planning and implementation of the research project. LECs may include individuals with a TBI or psychological health condition, their family members, or care partners. Ideally 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://icdr.acl.gov/resources/reports/getting-most-out-stakeholder-engagement-toolkit-better-understand-and-measure.

Required Data Sharing 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 Submission 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 allow for optional passive follow-up via electronic health record.
    - As applicable, applicants are strongly encouraged to include secondary outcomes in proposed studies to address potential crosscutting impacts of interventions.
    - 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 applicants to incorporate Common Data Elements (CDEs) appropriate to each field of study, such as the PhenX Core and Specialty collections***, which are available in the Mental Health Research, Substance Abuse and Addiction, and Research Domains Collections of the PhenX Toolkit, into all studies involving human subjects as applicable. Justification is required if the recommended measure in the PhenX Toolkit is not selected.
    - The TBIPHRP recommends that applicants consider the National Institute of Mental Health (NIMH) Data Archive (NDA) as a data-sharing repository for psychological health human subjects data. 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.
    - In order to share data with the NDA, these elements ***must be included*** in the proposed research:
        - Updated informed consent language that includes NDA data sharing. Sample consent language can be found in Appendix III.
        - NDA Global Unique Identifier (GUID): The NDA GUID is a subject ID that allows researchers to share data specific to a study participant without exposing personally identifiable information (PII) and makes it possible to match participants across labs and research data repositories. In order to generate an NDA GUID for a subject, the following PII ***must be collected in the proposed research*** *(this PII is never sent to the NDA)**:***

        - Complete legal given (first) name of subject at birth
        - Complete legal additional name of subject at birth (if subject has a middle name)
        - Complete legal family (last) name of subject at birth
        - Day of birth
        - Month of birth
        - Year of birth
        - Name of city/municipality in which subject was born
        - Sex at birth
    - In addition, for research participants aged 18 or over, the following data must be collected. ***The expectation to collect these data does not preclude the use of other data collection instruments that collect similar data***.
        - Age
        - DSM-5 crosscutting assessment (adult)
        - WHODAS 2.0
        - Patient Health Questionnaire - 9
        - GAD - 7
    - 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 awardees make TBI research data generated by this award mechanism available to the research community through the FITBIR Informatics System, a free resource designed to accelerate research progress by allowing the storage, reanalysis, integration, and rigorous comparison of multiple datasets. Currently, FITBIR-eligible research includes all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging and genetic). Consult the NDA website at https://fitbir.nih.gov for additional information.
    - In order to share data with the FITBIR, these elements ***must be included*** in the proposed research:
        - Updated informed consent language that includes FITBIR data sharing. Sample consent language is included in Appendix IV.

- FITBIR GUID: The FITBIR GUID is a subject ID that allows researchers to share data specific to a study participant without exposing PII and makes it possible to match participants across labs and research data repositories. In order to generate a GUID for a subject, the following PII ***must be collected in the proposed research*** *(this PII is never sent to the FITBIR system)**:***

  - Complete legal given (first) name of subject at birth
  - Complete legal additional name of subject at birth (if subject has a middle name)
  - Complete legal family (last) name of subject at birth
  - Day of birth
  - Month of birth
  - Year of birth
  - Name of city/municipality in which subject was born
  - Country of birth

- National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs: Research data elements ***must be reported*** using the NINDS TBI CDEs or entered into the FITBIR data dictionary as new, unique data elements (UDEs). For the most current version of the NINDS TBI CDEs, go to https://www.commondataelements.ninds.nih.gov. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure that the formats of the CDEs collected are compatible with the FITBIR Informatics System. Use of the TBI CDEs is required as applicable in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI. Applicants are strongly required to review TBI CDEs and associated form structures during the development of the study collection methods. ***If approved CDEs are not incorporated, justification is required and subject to program approval.***

- 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 guidance for either TBI research, psychological health research, or both as appropriate. Applicants are recommended to justify their choice.

The CDMRP expects to allot approximately $76.0M to fund approximately 10 Research Level 1, 16 Research Level 2, and 3 Research Level 3 FY23 TBIPHRP CTA proposals/ applications. Funding of proposals/applications received is contingent upon the availability of federal funds for this program as well as the number of proposals/applications received, the quality and merit of the proposals/applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY23 funding opportunity will be initially funded with FY23 funds, which will expire for use on September 30, 2029.

The USAMRDC executes its extramural research program primarily through the awarding of contracts and assistance agreements (grants and cooperative agreements). 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 (grant or cooperative agreement)*** is appropriate when the federal government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a ***grant*** award will be made (31 USC 6304).

Conversely, if substantial involvement on the part of the funding agency is anticipated, a ***cooperative agreement*** will be made (31 USC 6305) and the award will identify the specific substantial involvement. Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award.

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.

Please see Appendix 2, Section E, of the General Submission Instructions for more information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Refer to the General Submission Instructions, Appendix 3, for general eligibility information.

Note: In accordance with FAR 35.017, 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.

Government Agencies Within the United States: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

Proposals/applications for this BAA may only be submitted by extramural organizations. Submissions from intramural DOD organizations as the contracting organization 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 organization other than the DOD, and research institutes.

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: An application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

Note: Proposals/applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation. ***It is also permissible, however, for an intramural investigator to be named as a collaborator on a proposal/application submitted through an extramural organization. In this case, the proposal/application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.*** For more information, refer to the General Submission Instructions, Appendix 3 III.

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

II.C.1.b. Principal Investigator

Independent investigators at the level of Assistant Professor (or equivalent) are eligible to be named by the organization as the PI in the proposal/application.

II.C.1.c. Early-Career Investigator Partnering Option

The Early-Career Investigator must be an independent investigator within 10 years after completion of their terminal degree by the time of the proposal/application submission deadline (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is not excluded. ***Postdoctoral fellows are not considered independent investigators unless documentation is provided by the applicant's organization.*** 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.

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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 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 3, for additional information.

Conflicts of Interest (COIs): All awards must be free of COIs that could bias the research results. Prior to award of a contract, applicants will be required to disclose all potential or actual COIs along with a plan to manage them. An award may not be made if it is determined by the USAMRAA Grants/Contracting that COIs cannot be adequately managed. Refer to the General Submission Instructions, Appendix 3, for additional information.

Review of Risk: The following areas may be reviewed in evaluating the risk posed by an applicant: 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.

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

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 19.704, and Defense Federal Acquisition Regulation Supplement, Subpart 219.704 (DFARS 219.704). A

mutually agreeable plan will be developed during the award negotiation process and incorporated as part of the resultant contract.

In addition to other information provided herein, by submitting a proposal/application and accepting an award, the organization is (1) certifying that the applicants' credentials have been examined and (2) verifying that the applicants are qualified to conduct the proposed study and to use humans as research subjects, if proposed. Applicants include all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

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

II.D. Proposal/Application and Submission Information

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

Submission of proposals/applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative proposal(s)/ application(s). As an exception, applicants may submit the research project described in their FY23 TBIPHRP CTA proposal/application as part of a proposal/application to the FY23 TBIPHRP Focused Program Award (Funding Opportunity Number HT9425-23-S-TBIPH2); however, accepting multiple awards to support the same project will not be allowed.

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.

II.D.1. eBRAP and Grants.gov

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

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

To obtain the complete Grants.gov submission package, including all required forms, perform a Grants.gov (https://www.grants.gov/) basic search using the Funding Opportunity Number HT9425-23-S-TBIPH1.

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

Extramural Submission:

- Pre-proposal/pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full proposal/application packages must be accessed and submitted at Grants.gov.

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

Submission is a two-step process requiring both ***pre-proposal***/***pre-application*** (eBRAP.org) and ***full proposal/application*** (Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Refer to Table 1, Full Application Guidelines for full application submission guidelines.

Pre-Proposal/Pre-Application Submission: All pre-proposals/pre-applications must be submitted through eBRAP (https://eBRAP.org/).

Full Proposal/Application Submission: Full proposals/applications must be submitted through Grants.gov (https://www.grants.gov).

Full proposals/applications must be submitted through Grants.gov Workspace. Proposals/ applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DOD or other federal organizations or investigators will be considered extramural submissions. See definitions in Section II.C.1, Eligible Applicants.

eBRAP allows an organization's representatives and PIs to view and modify the full proposals/ application submissions associated with them. eBRAP will validate full proposal/application files against the specific BAA requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. It is the applicant's responsibility to review all proposals/application components for accuracy as well as ensure proper ordering as specified in this BAA.

The proposal/application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-proposal/pre-application and full proposal/application submission process. Inconsistencies may delay proposal/application processing and limit or negate the ability to view, modify, and verify the proposal/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 proposal/application submission deadline.

Research Level 1 Early-Career Investigator Partnering Option: The Initiating PI must complete the pre-proposal/pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified of the pre-proposal/ pre-application submission separately by email. The Partnering PI must follow the link in the notification email to associate the partnering pre-proposal/pre-application with their eBRAP account. After associating the pre-proposal/pre-application to their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated to their pre-proposal/pre-application. The email should include the pre-proposal/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). If not previously registered, the Partnering PI must register in eBRAP. A new pre-proposal/pre-application based on this research project should not be initiated by the Partnering PI. Applicants 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 proposal/application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full proposal/ application package components to eBRAP.

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

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

To begin the pre-proposal/pre-application process, first confirm that the submitting organization is extramural. If it is not, cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

Note: Although collaboration with intramural DOD organizations is encouraged, proposals/applications for this BAA may only be submitted by extramural organizations. Submissions from intramural DOD organizations directly to this BAA will be withdrawn.

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

All pre-proposal/pre-application components must be submitted by the PI (for single PI applicants) or Initiating PI (for applicants submitting under the Research Level 1 Early-Career Investigator Partnering Option) through eBRAP (https://eBRAP.org/). Because the invitation to submit a proposal/application is based on the contents of the pre-proposal/pre-application, investigators should not change the title or research objectives after the pre-proposal/pre-application is submitted.

The applicant organization and associated PI(s) identified in the pre-proposal/pre-application should be the same as those intended for the subsequent proposal/application submission. If any changes are necessary after submission of the pre-proposal/pre-application, the applicant must contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

No change in PI will be allowed after the pre-proposal/pre-application deadline. If any other changes are necessary after submission of the pre-application, the PI must contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

When starting the pre-proposal/pre-application, applicants will be asked to select a "Mechanism Option." Applicants are responsible for selecting the appropriate option for the pre-proposal/pre-application:

Proposal/Application 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

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

The pre-proposal/pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Submission Instructions, Section II.B, for additional information on pre-proposal/pre-application submission):

- **Tab 1 –Application Information**

  Submission of proposal/application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 –Application Contacts**

  Enter contact information for the PI(s). Enter the organization's Business Official(s) responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-proposal/pre-application to be submitted.

  Select the performing organization (site at which the PI[s] will perform the proposed work) and the contracting organization (organization[s] submitting on behalf of the PI[s], which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on "Add Organizations to this Pre-application." The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-proposal/pre-application to be submitted.

  It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-proposal/pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

  Enter the name, organization, and role of all collaborators and key personnel associated with the proposal/application.

  CBPR: Identify by name the patients, caregivers, patient advocates, or community leaders that will support the CBPR approach**.** ***CBPR team members cannot be employees of any of the organizations participating in the proposal/application.*** Include any relevant details regarding their experience with TBI/psychological health conditions and/or organizational/advocacy affiliations. *(For administrative purposes, please use the label "Consumer" when assigning the LEC or community-based partners' roles in eBRAP.)*

  FY23 TBIPHRP Programmatic Panel members should not be involved in any pre-proposal/ pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

  Research Level 1 Early-Career Partnering Option: The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Proposal/Pre-Application Files**

  Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  - **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 at least one sub-area within one of the three FY23 TBIPHRP CTA Focus Areas.

    – **Rationale:** Briefly describe the scientific rationale, intervention and intervention's readiness to support the initiation of the proposed clinical trial; include relevant 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 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 a promising intervention into clinical application. Explain how the project is relevant to the health care needs of Service Members, Veterans, and/or military beneficiaries.

- **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.

  Refer to the General Submission Instructions, Section II.B, for detailed information.

- **Tab 6 – Submit Pre-Proposal/Pre-Application**

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

Pre-Proposal/Pre-Application Screening

- **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 at least one sub-area within one of the three FY23 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 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 a promising intervention into clinical application. How well the research is relevant to the health care needs of Service Members, Veterans, and/or military beneficiaries.

- **Notification of Pre-Proposal/Pre-Application Screening Results**

  Following the pre-proposal/pre-application screening, PI(s) will be notified as to whether they are invited to submit proposals/applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposal/pre-application. The estimated timeframe for notification of invitation to submit a proposal/application is indicated in Section I, Overview of the Funding Opportunity. Invitations to submit a full proposal/application are based on the Pre-Proposal/Pre-Application Screening Criteria listed above.

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

Proposals/applications will not be accepted unless notification of invitation has been received by the PI or Initiating PI.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each proposal/application submission must include the completed full proposal/application package for this BAA. The full proposal/application package is submitted by the Authorized Organizational Representative through Grants.gov (https://www.grants.gov/). See Table 1 below for more specific guidelines.

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

Extramural organizations must submit full proposals/applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the proposal/application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit a proposal/application package consisting of PDF forms. If more than one person is entering text into a proposal/application package, the ***same version*** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Submission Instructions, Section III, and the "Apply For Grants" page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural proposals/applications through eBRAP may be withdrawn.

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

Table 1. Full Application Submission Guidelines

Proposal/Application Package Location
Download proposal/application package components for HT9425-23-S-TBIPH1 from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the proposal/application components and routing of the proposal/ application package through the applicant organization for review prior to submission.
Full Proposal/Application Package Components
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Submission Instructions, Section III.A.1, for detailed information.
Descriptions of each required file can be found under Full Proposal/Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form
Proposal/Application Package Submission
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.

Submit a Grants.gov Workspace Package.
A proposal/application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the proposal/application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the proposal/application submission.

Note: If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to*** the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***

Proposal/Application Verification Period

The full proposal/application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the proposal/application verification period. During the proposal/application verification period, the full proposal/application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***.

Further Information

Tracking a Grants.gov Workspace Package.
After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission.

Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

Research Level 1 Early-Career Investigator Partnering Option: In order to make separate awards to each PI, CDMRP requires separate full proposal/application 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 proposal/application 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 proposal/application submission deadline.***

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

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

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

- **Attachments:**

  Each attachment to the full proposal/application 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 4.

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

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

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

    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 at least one sub-area within one of the three FY23 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 Attachments 12 and 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.

  - Provide a brief description about how CBPR will be implemented in the study design. ***Full details of the CBPR approach should be provided in Attachments 12 and 13.***

  - 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 an 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 proposal/application.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

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

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

– **Women and Minorities in the Study:** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Describe the strategy for the inclusion of women and minorities 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) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **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):** 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):** If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating the availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.

- **Letters of Collaboration (if applicable) (two-page limit per letter):** Provide a signed letter from each collaborating individual or organization demonstrating that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on a proposal/application submitted through an extramural organization, the proposal/application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes 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 FY23 TBIPHRP CTA are subject to a federal purpose license. A term of the FY23 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. Refer to the General Submission Instructions, Appendix 2, Sections C and D, for more information about disclosure of proprietary information.

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 and resources generated during the performance of the project will be shared with the research community, including the sharing of de-identified data with repositories. As appropriate, provide the Data and Research Resources Sharing Plan for the research project proposed. Refer to the General Submission Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available. Information on selecting a repository can be found here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-016.html. Other NIH-supported Data Sharing Resources 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.
- For UDEs, 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 psychological health human subjects research:

- Identify, describe, and justify the choice for the intended data-sharing platform.
- Identify and describe the planned CDEs appropriate to each field of study, such as the PhenX Core and Specialty collections.
- Provide justification if the recommended measure in the PhenX Toolkit is not selected.

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

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

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

- **Attachment 3: Technical Abstract (one-page limit each): 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:** Briefly describe the study design, including model system(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 FY23 TBIPHRP CTA Focus Areas to be addressed.

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

- **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 proposal/application 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 in a manner that can be ***readily understood by readers without a background in science or medicine.***

- Describe the CBPR approach and implementation in the study.

- Describe the ultimate applicability of the research and how it addresses at least one ***sub-area within one of the three*** FY23 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, Veterans, and/or military beneficiaries

- **Attachment 5: Statement of Work (seven-page limit): Upload as "SOW.pdf".** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

  For the FY23 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 proposal/application 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-eligible research should include:
  - FITBIR investigator and study registration within the first 30 days of the award
  - Sharing of draft data collection forms with FITBIR
  - Annual FITBIR data submissions

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 the clinical needs. 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. Provide evidence indicating availably of the intervention from its source for the duration of the proposed clinical trial (if applicable). Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the proposed clinical trial.

    Summarize key preclinical pharmacological findings, dosage studies, and other clinical evidence (if applicable) that examine the safety and stability (as appropriate) of the intervention. Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
  - **Study Procedures:** Describe the interaction with the human subject, including the study intervention that they will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Clearly delineate research procedures from routine clinical procedures. Discuss how compliance with current Good Laboratory Practice (GLP) guidelines, Good Manufacturing Practice (GMP), and other regulatory considerations will be established, monitored, and maintained, as applicable.

- **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for current ICH E6 (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Good Clinical Practice (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 and retention goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical research/trial(s) (if applicable). Identify any potential barriers to accrual/retention and provide mitigation plans for addressing unanticipated delays (e.g., slow accrual, attrition). Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress. 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.

  - **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.

    - If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.

- Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

– **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. Applications planning to share data with the NIH NDA and/or the FITBIR-eligible applications should include the appropriate consent language for the NDA or FITBIR. See Appendices III and IV for sample consent language.***

    - 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. 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 proposal/application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the

proposed clinical trial. If applicable, refer to the General 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. Study risks include any risks that the human subject is exposed to as a result of participation in the proposed clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. Consider how the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

- **Risk management and emergency response:**

  - Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and 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.

  - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).

  - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment

(e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.

- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge 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.").

– **Laboratory Evaluations:**

- **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.

- **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).

- **Storage:** Describe specimen storage, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use, including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.

- **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

– **Questionnaires and Other Research Data Collection Instruments, if applicable:**

- Provide 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. If the adaptation results in a deviation from validated instruments, please justify.

- **Attachment 8: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Answer the following questions and provide supporting documentation as applicable. For the FY23 TBIPHRP CTA, evidence investigational product regulatory exemption (e.g., IND/IDE) application submission or authorization without clinical hold status must be included in the FY23 TBIPHRP CTA proposal/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 FY23 TBIPHRP CTA ***evidence that an investigational product regulatory exemption application (e.g., IND/IDE) has been submitted, cleared, or authorized without clinical hold status must be included in the proposal/application.*** 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 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 submission within the proposal/application***. 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).

- Describe the overall regulatory strategy and product development plan that will support the planned product indication or product label change (if applicable). 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 unless documentation is provided by the applicant's organization.*** 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".** Describe/discuss the methods and strategies proposed to move the intervention to the next phase of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The post-award transition plan should include the components listed below.

  - Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.

  - 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.).

  - A brief schedule and milestones for transitioning the intervention (e.g., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval a Regulatory Agency).

- 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.

- A risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 11: Impact and Relevance to Military Health Statement (five-page limit): Upload as "Impact.pdf".** The Impact and Relevance to Military Health Statement must demonstrate alignment with at least one sub-area within the FY23 TBIPHRP CTA Focus Areas and 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 at least one sub-area within one of the three FY23 TBIPHRP CTA Focus Areas.

  - ***Describe the near-term impact:*** Detail the anticipated outcomes that will be directly attributed to the results of the proposed clinical trial and describe anticipated short-term benefits for individuals.

  - ***Describe the long-term impact:*** Explain the long-range vision for implementation of the intervention in the clinic or field and describe the anticipated long-term benefits on patient care and/or quality of life for the targeted population.

    - Describe any relevant controversies or treatment issues that will be addressed by the proposed clinical trial.

    - Describe any potential issues that might limit the impact of the proposed clinical trial.

    - Describe how the intervention represents an improvement over currently available interventions and/or standards of care.

  - Describe how the proposed effort is responsive to the health care needs of Service Members, Veterans, and/or military beneficiaries.

    - 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 United States Food and Drug Administration.*** 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 12: CBPR Letters of Commitment (two-page limit per letter): Start each document on a new page. Combine and upload as "CBPR_letter.pdf.** Provide a letter signed by each LEC 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.

- **Attachment 13: CBPR Statement (three-page limit): Start each document on a new page and clearly identify the supported project(s) or overall program. Combine and upload as "CBPR_PI.pdf".** Provide a statement that includes:

  - Description of the CBPR approach that will be used (e.g., LEC, 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 Collaborating DOD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or DOD

activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using "Suggested Collaborating DOD Military Facility Budget Format", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Submission Instructions, Section III.A.8, for detailed information.

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: Refer to the General Submission Instructions, Section III.A.3, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): Refer to the General Submission Instructions, Section III.A.4, for detailed information.

- PI Biographical Sketch (six-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

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

  - Refer to the General Submission Instructions, Section III.A.4, for detailed information.

- 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".

  - Refer to the General Submission Instructions, Section III.A.4, for detailed information.

Research & Related Budget: Refer to the General Submission Instructions, Section III.A.5, for detailed information.

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

Research Level 1 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 proposal/application packages. The Initiating PI should not include budget information for Partnering PI even if they are located within the same organization. Refer to Section II.D.6, Funding Restrictions, for detailed information.

Project/Performance Site Location(s) Form: Refer to the General Submission Instructions, Section III.A.6, for detailed information.

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

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

  Note: Proposals/applications from **federal agencies** must include a **Federal Financial Plan** in their budget justifications. Proposals/applications from organizations that include **collaborations with DOD military facilities** must comply with special requirements. Refer to the General Submission Instructions, Section III.A.5, for detailed information.

Application Components for the Partnering PI if applying under the Research Level 1 Early-Career Investigator Partnering Option

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

For the Partnering PI, the Initiating PI must confirm if the Partnering PI will be named on an extramural proposal/application (in accordance with the guidelines in Section II.C.1.a, Organization). ***Proposals/applications for this BAA may only be submitted by extramural organizations.*** The Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their proposal/application.

The proposal/application submission process for the Partnering PI uses an abbreviated full proposal/application package that includes:

Attachments:

- **Attachment 5: Statement of Work (seven-page limit): Upload as "SOW.pdf".** Refer to the General Submission Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.

- **Attachment 14: Representations: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Submission Instructions, Appendix 5, Section B, Representations.

- **Attachment 15: Suggested Collaborating DOD Military Facility Budget Format: Upload as "MFBudget.pdf".** Refer to the General Submission Instructions, Section III.A.8, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

Research & Related Personal Data: Refer to the General Submission Instructions, Section III.A.3, for detailed information.

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

- PI Biographical Sketch (six-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

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

  - Refer to the General Submission Instructions, Section III.A.4, for detailed information.

- 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".

- Refer to the General Submission Instructions, Section III.A.4, for detailed information.

Research & Related Budget: Refer to the General Submission Instructions, Section III.A.5, for detailed information.

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

Research Level 1 Early-Career Investigator Partnering Option: Initiating and Partnering PIs must have a separate budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP proposal/application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.6, Funding Restrictions, for detailed information.

Project/Performance Site Location(s) Form: Refer to the General Submission Instructions, Section III.A.6, for detailed information.

Research & Related Subaward Budget Attachment(s) Form:

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Submission Instructions, Section III.A.7, for detailed information.)

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

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

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/SAM/) and receive confirmation of an "Active" status before submitting an application through Grants.gov. ***As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.*** Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Proposal/Application Submission in eBRAP

eBRAP allows an organization's representatives and PIs to view and modify the full proposal/ application submissions associated with them. Following retrieval and processing of the full proposal/application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full proposal/application submission. eBRAP will validate full proposal/application files against the FY23 TBIPHRP CTA requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. Proposal/application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all proposal/application components and ensure proper ordering as specified in the FY23 TBIPHRP CTA. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full proposal/application package must be submitted prior to the proposal/application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the proposal/ application submission deadline.*** Other proposal/application components may be changed until the end of the proposal/application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the proposal/application verification period. If these components are missing, upload them to eBRAP before the end of the proposal/application verification period. After the end of the proposal/application verification period, the full proposal/application cannot be modified.

The full proposal/application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the proposal/application verification period. During the proposal/ application verification period, the full proposal/application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

Verify that subaward budget(s) with budget justification are present in eBRAP during the proposal/application verification period. If these components are missing, upload them to eBRAP before the end of the proposal/application verification period.

II.D.5. Intergovernmental Review

This BAA is not subject to Executive Order (EO) 12372, "Intergovernmental Review of Federal Programs." The EO provides for state and local government coordination and review of proposed federal financial assistance and direct federal development. The EO allows each state to designate an entity to perform this function. This coordination and review is not required under this BAA.

II.D.6. Funding Restrictions

For Research Level 1

- The maximum period of performance is **3** years.
- The 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.

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.
- The applicants may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years. The duration of the period of performance for the Initiating PI and Partnering PI should be the same.
- A separate award will be made to each PI's organization.

For Research Level 2

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

For Research Level 3

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

  The 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.

For all proposal/applications:

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

- Single PI: Travel costs for the PI to present project information or disseminate project results at two separate DOD-sponsored meeting to be specified by the program office during award negotiations (e.g., Interim/In-Progress Review [IPR] meeting or Military Health System Research Symposium).
- Early-Career Investigator Partnering Option: Travel costs for the Initiating and Partnering PIs to present project information or disseminate project results at two separate DOD-sponsored meeting to be specified by the program office during award negotiations (e.g., IPR meeting or Military Health System Research Symposium).

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 FY23 TBIPHRP CTA.
- Early-Career Investigator Partnering Option: Starting in year two, 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 FY23 TBIPHRP CTA.
- Costs associated with CBPR implementation
- 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.

Awards made to extramural organizations will consist of contracts or assistance agreements (grants and cooperative agreements). For extramural awards with an intragovernmental

component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer.

Refer to the General Submission Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. ***For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Submission Instructions, Section III.A.5.***

II.D.7. Other Submission Requirements

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

II.E. Proposal/Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all proposals/applications will be 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 proposal/application 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.
    - How well plans to collect specimens and conduct laboratory evaluations are relevant to the study objectives, if applicable.
    - 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 proposal/application 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 proposal/application 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 is appropriate to the objectives of the study.
    - Whether the distribution of the proposed enrollment on the basis of sex/gender, race, and/or ethnicity is appropriate for the proposed research.
- **Intervention**
    - 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.
    - How the intervention compares with currently available interventions and/or standards of care.
    - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention
    - How well research procedures are clearly delineated from routine clinical procedures.
    - Whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
- **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.
    - How the overall regulatory strategy and product development plan that will support the planned product indication or product label change.

- As appropriate, whether the proposal/application includes evidence that the investigational product regulatory exemption (e.g., IND/IDE) has been submitted or authorized without clinical hold status.

- 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 identified next level of development and/or commercialization is realistic.

- Whether the funding strategy described to bring the intervention to the next level of development (e.g., specific industry partners, specific funding opportunities to be applied for) is reasonable and achievable.

- For knowledge products, whether the proposed collaborations and other resources are achievable to provide continuity of development.

- Whether the schedule and milestones for bringing the intervention to the next level of development (next-phase clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, and/or approval by a Regulatory Agency) are achievable.

- Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.

- How well the proposal/application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization.

- If applicable, how well the proposal/application describes an appropriate intellectual and material property plan among participating organizations.

- If applicable, how well the proposal/application 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 on the lives and health of the target population with regard to the FY23 TBIPHRP CTA Focus Areas.

  - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.

- How the anticipated outcomes of the proposed clinical trial will provide/improve short-term benefits for individuals.

- How significantly the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.

- **Relevance to Military Health**

  - If applicable, whether the proposed research is likely to enhance readiness and recovery on the battlefield, during training, or in resource-limited environments.

  - If applicable, how well the proposed research project complements DOD and/or VA areas of research interest and/or patient care for psychological health conditions and/or TBI.

  - Whether the study's knowledge, information, products, or technologies could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.

- **Ethical Considerations**

  - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.

  - Whether the population selected to participate in the trial stands to benefit from the knowledge to be gained as a result of the proposed research.

  - 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**

  - To what degree the statistical model and data analysis plan is suitable for the planned study.

  - 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.

  - If applicable, to what extent the study team composition is able to provide military-relevant subject matter expertise to the proposed research.

  - 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.

  - As applicable, how thoroughly the proposal/application identifies and describes the intended NINDS TBI and/or PhenX CDEs to be used.

  - If applicable, how thoroughly the proposal/application justifies any instances where existing CDEs are not applicable or appropriate.

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 proposal/application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY23 TBIPHRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Relative impact and military benefit

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

All proposals/applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of proposals/applications against established criteria to determine technical merit, where each proposal/application is assessed for its own merit, independent of other proposals/applications. The second tier is **programmatic review**, a comparison-based process in which proposals/applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring proposals/ applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess. An information paper describing the funding recommendations and review process for the FY23 TBIPHRP CTA will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that proposal/application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's proposal/application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in FAPIIS.

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the DoDGARs, Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

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

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY23 funds are anticipated to be made no later than September 30, 2024. Refer to the General Submission Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs *(Assistance Agreements Only)*: An institution of higher education, hospital, non-profit or for-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Submission Instructions, Section III.A.5.

Only an appointed USAMRAA Grants/Contracting Officer may obligate the government to the expenditure of funds. No commitment on the part of the government should be inferred from

discussions with any other individual. **The award document signed by the Grants/ Contracting Officer is the official authorizing document.**

Federal Government Organizations: Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

II.F.1.a. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI will be allowed at the discretion of the Grants/ Contracts Officer, provided the intent of the award mechanism is met.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants/Contracts Officer.

An organizational transfer of an award supporting the Initiating PI or Partnering PI is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants/Contracts Officer.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Submission Instructions, Appendix 2, Section B, for general information on PI or organization changes.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this 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 V.

Refer to the General Submission Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Submission Instructions, Appendix 5, for general information regarding national policy requirements.

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

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

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

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

II.F.3. Reporting

Refer to the General Submission Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

Quarterly progress reports and Quad Charts will be required.

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

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

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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

Awards resulting from the FY23 TBIPHRP CTA may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than

$10M are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Submission Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions related to content or submission requirements in the FY23 TBIPHRP CTA as well as questions related to the pre-proposal/pre-application submission through eBRAP should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the eBRAP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the "Synopsis" page for the MMRDA or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Administrative Actions

After receipt of pre-proposals/pre-applications or proposals/applications, 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 proposal/application:

- Submission of a proposal/application for which a letter of invitation was not received.
- 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 and Relevance to Military Health Statement (Attachment 11) is missing.
- CBPR Letters of Commitment (Attachment 12) is missing.
- CBPR Statement (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 Preproposal Narrative and Proposal/Application Project Narrative.
- Documents not requested will be removed.

II.H.1.c. Withdrawal

The following may result in administrative withdrawal of the pre-proposal/pre-application or proposal/application:

- An FY23 TBIPHRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-proposal/pre-application or proposal/application processes including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. ***A list of the FY23 TBIPHRP Programmatic Panel members can be found at https://cdmrp.health.mil/tbiphrp/panels/panels23.***

- The proposal/application 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY23, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Proposals/applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Proposal/application includes classified research information and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security.
- Proposal/application is submitted by an intramural DOD organization as the contracting organization.
- Proposal/application consists solely or primarily of planning, engineering, manufacturing, or formulation activities.
- The invited proposal/application 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.
- Proposal/application does not include a CBPR approach.
- Submission of the same research project to different funding opportunities within the same program and fiscal year. Refer to Section II.D, Application and Submission Information, for exceptions.

- Application failed to address at least one sub-area within one of the three FY23 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.

- If the proposed clinical trial of an investigational product will be conducted at international sites, no evidence is provided that an application to the relevant national regulatory agency of the host country(ies) has been submitted or approved without clinical hold.

- Proposal/Application does not demonstrate support for and access to relevant population(s) and/or resources(s).

II.H.1.d. Withhold

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

II.H.2. Proposal/Application Submission Checklist

Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed
SF424 Research & Related Application for Federal Assistance	Complete form as instructed		
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"		
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"		
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"		
	Lay Abstracts: Upload as Attachment 4 with file name "LayAbs.pdf"		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"		
	Intervention: Upload as Attachment 6 with file name "Intervention.pdf"		
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 7 with file name "HumSubProc.pdf"		
	Regulatory Strategy: Upload as Attachment 8 with the file name "Regulatory.pdf"		
	Study Personnel and Organization: Upload as Attachment 9 with file name "Personnel.pdf"		
	Transition Plan: Upload as Attachment 10 with file name "Transition.pdf"		
	Impact and Relevance to Military Health Statement: Upload as Attachment 11 with file name "Impact.pdf"		
	CBPR Letters of Commitment: Upload as Attachment 12 with file name "CBPR_letters.pdf"		
	CBPR Statement: Upload as Attachment 13 with file name "CBPR_PI.pdf"		
	Representations (extramural submissions only): Upload as Attachment 14 with file name "RequiredReps.pdf"		

Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 15 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field		
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed		

APPENDIX I: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ASR	Acute Stress Reaction
BAA	Broad Agency Announcement
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
EC	Ethics Committee
EFIC	Exception from Informed Consent
EO	Executive Order
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
GUID	Global Unique Identifier
IDE	Investigational Device Exemption
IND	Investigational New Drug
IPR	Interim/In-Progress Review
IRB	Institutional Review Board
LAR	Legally Authorized Representative

LEC	Lived Experience Consultation (or Consultant)
M	Million
MB	Megabyte
MIPR	Military Interdepartmental Purchase Request
NDA	NIMH [National Institute of Mental Health] Data Archive
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
NPC	Non-Profit Corporation
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORCID	Open Researcher and Contributor ID, Inc.
PHS	Public Health Service
PI	Principal Investigator
PII	Personally Identifiable Information
PTSD	Posttraumatic Stress Disorder
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
TBIPHRP	Traumatic Brain Injury and Psychological Health Research Program
UDE	Unique Data Element
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 II: DOD and VA WEBSITES

Principal Investigators are encouraged to integrate and/or align their research projects with Department of Defense (DOD) and/or Department of Veterans Affairs (VA) research laboratories and programs. Collaboration with DOD 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.

Advanced Research Projects Agency for Health

https://arpa-h.gov/

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/dha

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/

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

Naval Medical Research Center
https://www.med.navy.mil/

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

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

Psychological Health Center of Excellence
https://health.mil/Military-Health-Topics/Centers-of-Excellence/Psychological-Health-Center-of-Excellence

Psychological Health and Traumatic Brain Injury Research Program Research Resources
https://cdmrp.health.mil/phtbi/resources/phtbiresources.aspx

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

Traumatic Brain Injury Center of Excellence
https://health.mil/Military-Health-Topics/Centers-of-Excellence/Traumatic-Brain-Injury-Center-of-Excellence

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

U.S. Air Force 59th Medical Wing
https://www.59mdw.af.mil/

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

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

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 Defense Sexual Assault Prevention and Response Office
https://www.sapr.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 III: SAMPLE NDA CONSENT LANGUAGE

Data from this study will be submitted to the National Institute of Mental Health (NIMH) Data Archive (NDA) at the National Institutes of Health (NIH). The NDA is a large database where de-identified study data from many NIH studies are stored and managed. Sharing your de-identified study data helps researchers learn new and important things about brain science more quickly than before.

De-identified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to the NDA.

It is possible that you will participate in more than one study that sends data to the NDA. The NDA can connect your data from different studies by matching the code number on your de-identified data from each study. This data matching helps ensure that researchers who use NDA data only count you one time. It also helps researchers who use the NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send de-identified study data about your health and behavior to the NDA. Other researchers across the world can then request your de-identified study data for different research projects. Every researcher (and the institution to which they belong) who requests your de-identified study data must promise to keep your data safe and not try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are low; however, your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with the NDA. The study data provided to the NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. The NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to the NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell the NDA to stop sharing your study data. Once your data are part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about the NDA, it is available online at http://nda.nih.gov.

APPENDIX IV: SAMPLE FITBIR CONSENT LANGUAGE

Data from this study may be submitted to the Federal Interagency Traumatic Brain Injury (FITBIR) informatics system. FITBIR is a computer system run by the National Institutes of Health (NIH) that allows researchers studying traumatic brain injury to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about traumatic brain injury more quickly than before.

During and after the study, the researchers will send information about you or your child's health and behavior and, in some cases, you or your child's genetic information to FITBIR. However, before they send it to FITBIR, they will remove information such as name, date of birth, and city of birth and replace that information with a code number. Other researchers nationwide can then file an application to obtain access to your study data for research purposes. Experts who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You or your child may not benefit directly from allowing your information to be shared with FITBIR. The information provided to FITBIR might help researchers around the world treat future children and adults with traumatic brain injury so that they have better outcomes. FITBIR will report on its website about the different studies that researchers are conducting using FITBIR data; however, FITBIR will not be able to contact you or your child individually about specific studies.

You may decide now or later that you do not want to share you or your child's information using FITBIR. If so, contact the researchers who conducted this study and they will tell FITBIR to stop sharing the research information. However, FITBIR cannot take back information that was shared before you changed your mind. If you would like more information about FITBIR, this is available online at http://fitbir.nih.gov.

Language to be used to describe certificates of confidentiality (three versions):

1. Language for new studies that will be consenting subjects for the first time or for ongoing studies that will be re-consenting subjects because they are applying for a Certificate of Confidentiality for the study

To help protect you and/or your child's privacy, the investigators of this study [have applied for]/[have obtained] a Certificate of Confidentiality from the National Institutes of Health (NIH), which is part of the U.S. Department of Health and Human Services (HHS), an U.S. Government agency.

With this Certificate, we, the investigators, cannot be forced (e.g., by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Be aware that disclosure of you and/or your child's identity may be found necessary, however, upon request of the HHS for the purpose of audit or evaluation.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note, however, that if an insurer or employer learns about you and/or your child's participation and obtains your consent to receive research information, then

the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

We are also asking your consent to provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. FITBIR is a biomedical informatics system and data repository, created by the Department of Defense and the National Institutes of Health to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat, and prevent traumatic brain injuries.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by qualified researchers only. Data provided to FITBIR as part of you and/or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will retain individually identifying information related to the data they provide, the NIH has issued a legislatively authorized "Certificate of Confidentiality" that will help FITBIR and participating institutions avoid being forced to disclose information that may identify you as a FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you, your child, or others. With respect to you and/or your child's participation in FITBIR, we do not plan to make voluntary disclosures except in response to severe threats to the public health or safety.

2. Language for studies that already have a Certificate and will be re-consenting subjects about FITBIR

With your consent, this study will collect and provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and National Institutes of Health (NIH)—part of the U.S. Department of Health and Human Services (HHS), an agency of the U.S. Government—to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injury.

Data entered into FITBIR will be kept confidential, as FITBIR is designed for access by researchers only. Data provided to FITBIR as part of you and/or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will retain individually identifiable information related to the data they provide, the NIH has issued a legislatively authorized "Certificate of Confidentiality" to help FITBIR and participating institutions avoid being forced (e.g., by court subpoena) to disclose information that may identify you as an FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Be aware that disclosure of you and/or your child's identity may be found necessary, however, upon request of the HHS for the purpose of audit or evaluation.

As you know, we have obtained a Certificate of Confidentiality from NIH that enables us to keep the individually identifiable information that you provide as a research subject private. With this Certificate, we, the investigators cannot be forced to disclose research information collected in this study that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. This protection will continue to protect you and/or your child's privacy even though we are providing de-identified data to FITBIR.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note, however, that if an insurer or employer learns about you and/or your child's participation and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Finally, as we explained when we told you about this privacy protection before, we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you and/or your child or others based on information they learn during this study. With respect to you and/or your child's participation in FITBIR, we do not plan to make voluntary disclosures except if there were severe threats to the public health or safety.

3. Language for studies without a Certificate of their own

With your consent, this study will collect and provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and the National Institutes of Health (NIH)—part of the U.S. Department of Health and Human Services, an agency of the U.S. Government—to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injury.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of you or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will still retain individually identifying information related to the data provided, the NIH has issued a legislatively authorized "Certificate of Confidentiality" to help FITBIR and participating institutions avoid being forced (e.g., by court subpoena) to disclose information that may identify you as an FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are also permitted to make voluntary disclosures with respect to information that is submitted to FITBIR, but do not plan to do so except in the event of severe threats to public health or safety. If, as part of your participation in this research study itself, we learn about serious harm to you, your child or someone else, we would take steps to prevent that harm including notifying appropriate authorities like the police or child welfare.

APPENDIX V: FAR 7 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 Broad Agency Announcement. Additional clauses apply based upon contract type. 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
52.209-9	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
252.203-7005	Representation Relating to Compensation of Former DoD Officials
252.204-7004	Alternate A, System for Award Management
252.204-7008	Compliance with Safeguarding Covered Defense Information Controls
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting

# Provision	Clause
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
252.204-7019	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
252.225-7060	Prohibition on Certain Procurements from the Xinjiang Uyghur Autonomous Region