

## **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**

**Focused Program Award**

**Announcement Type: Initial**

**Funding Opportunity Number: HT9425-23-S-TBIPH2**

**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.”*

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## 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 Focused Program Award (FPA). For the remainder of the announcement, this BAA will be referenced as the FY23 TBIPHRP FPA. 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 FPA 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, 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 FPA Focus Areas**

The FY23 TBIPHRP has identified the following Focus Areas for funding under the FY23 TBIPHRP FPA. To meet the intent of the award mechanism, proposals/applications ***must address at least one sub-area (1a, 1b, 2a, 2b, etc.)*** within one of the three FY23 TBIPHRP FPA 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 FPA Focus Area(s) 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 of risk, protective, and biological factors contributing to an individual’s vulnerability to, response to, and long-term outcomes of psychological health conditions and/or TBI. Studies with an objective biomarker component are allowed. Research of interest includes, but is not limited to:
    - Understanding psychological health trajectories associated with trauma (e.g., acute stress reactions [ASRs], adjustment disorders, posttraumatic stress disorder [PTSD]) and suicidality that incorporate internal and external factors. For example, factors could include time course, demographic characteristics, career progression, history of trauma exposure, and community and cultural factors.
    - Understanding how the approach to psychiatric diagnosis (e.g., ASRs, adjustment disorders, PTSD) in the military relates to occupational impairment and/or military separation.
    - Understanding the role of genetics, endophenotypes, health demographics, previous injuries or repetitive exposures, psychological health conditions, pathophysiology, and environmental factors (e.g., extreme temperatures/pressures) on TBI.

- Understanding the contribution of pre- and post-injury patient, family,<sup>1</sup> and caregiver education, as well as cultural, demographic, stigma, and bias factors that may relate to treatment-seeking and adherence.
  - Development and analysis of modeling from clinical data and other human data (e.g., electronic health records, exposure, training, and/or occupational data) to forecast the long-term and/or late effects of brain exposures, such as TBI, and co-occurring conditions.
  - Development and analysis of communication and tools/technology adoption that would facilitate clinical translation and identification of risk factors, educational barriers, social determinates of health, and other factors that may impede clinical translation.
- b. 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 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.
  - 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).
  - Understanding the psychological health consequences of intimate partner and family violence.
2. **Prevent and Assess:** Research will address the prevention or progression of psychological health conditions and/or TBI conditions through population, selective, and indicated

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<sup>1</sup> In the context of the FY23 TBIPHRP FPA Focus Areas, “family” should be broadly defined to include not just spouses, but also parents, significant others/fiancés/partners, children, caregivers, or close friends.

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 ASRs and PTSD or adjustment disorders may be proposed.
  - Preparation of Service Members and units for missions and to help reset and improve resilience between deployments.
  - Effective solutions to support relationships and parenting, prepare families for potential secondary trauma exposure, and empower families to access tailored support and resources.
- 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 FPA was first offered in FY21. Since then, 45 FPA proposal/applications have been received, and 7 have been recommended for funding.

### **II.B. Award Information**

The intent of the FY23 TBIPHRP FPA is to optimize research and accelerate solutions to a critical question related to at least one sub-area within one of the three FY23 TBIPHRP FPA Focus Areas. The award mechanism supports development of a synergistic, multidisciplinary research program 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. Proposals/applications may propose applied/preclinical/clinical research and clinical trials. Clinical trials may be designed to evaluate promising new products, new indications, pharmacologic agents (drugs or biologics), devices, clinical guidance, and/or emerging approaches and technologies. Hypothesis-driven health services research, implementation science, and follow-up care research are also within scope for this mechanism. Proposed clinical trials should demonstrate feasibility or inform the design of more advanced trials that determine efficacy in relevant patient populations.

Key aspects of the FY23 TBIPHRP FPA include:

**Overarching Challenge:** FPA proposals/applications must describe a unifying, overarching challenge that will be addressed by the set of research projects proposed. The overarching challenge must be relevant to a critical problem or question in the field of research and/or patient care in at least one sub-area within one of the three FY23 TBIPHRP FPA Focus Areas.

**Research Projects:** Proposals/applications shall include multiple, distinct research projects led by individual project leaders that address complementary aspects of the overarching challenge. Applicants are strongly encouraged required to *submit a minimum of four research projects, of which, a clinical research/trial research project is encouraged*. If the intent of the FY23 TBIPHRP FPA is maintained, proposals/applications including more or fewer than four projects are allowed. While individual projects must be capable of standing on their own high scientific merits, they must also be interrelated, synergistic, and align with the overarching challenge to advance a solution beyond what would be possible through individual efforts. The exploration of multiple hypotheses or viewpoints of the same line of questioning is encouraged. *This award mechanism is not intended to support a series of research projects that are dependent on the success of one of the other projects*. Each project should propose a unique approach to addressing the overarching challenge and be capable of producing research findings with potential to impact the field and/or patient care. *Individual research projects may include applied research, preclinical research, clinical research, and clinical trials. Proposed research projects should not include basic research<sup>2</sup>*. Preliminary data should be included to support each project's hypothesis/objective(s). There should be a clear intent to progress toward translational/clinical work over the course of the effort.

**Implementation:** The research strategy to address the overarching challenge must be supported by a detailed implementation plan that identifies critical milestones and outlines the knowledge, resources, and technical innovations that will be utilized to achieve the milestones. A robust statistical plan and statistical expertise should be included where applicable. A plan for assessing individual project performance and progress toward addressing the overarching challenge must be included in the implementation plan. Plans to include an External Advisory Board (EAB) are encouraged; however, applicants must be careful to avoid potential conflicts of interest (COIs) during review of the proposal/application by ensuring no contact with, recruiting of, or naming of specific EAB members in the proposal/application. For multi-institutional collaborations, plans for communication and data transfer among the collaborating institutions, as well as how data, specimens, and/or products obtained during the study will be handled, must

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<sup>2</sup> Basic research is defined as research directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward process or products in mind.

be included. An appropriate intellectual and material property plan agreed to by participating organizations is required in the proposal/application's supporting documentation.

**Research Team:** The overall effort will be led by a Principal Investigator (PI) with demonstrated success in leading large, focused collaborative projects. The PI is required to devote a minimum of 20% effort to this award. The PI should create an environment that fosters and supports collaboration and innovation in a way that engages all members of the team in all aspects of the research plan. The research team assembled by the PI should be highly qualified and multidisciplinary, with identified project leaders for each of the complementary and synergistic research projects. The resources and expertise brought to the team by each project leader should combine to create a robust, synergistic collaboration. The TBIPHRP Science Officer assigned to a resulting award should be invited to participate in research team meetings (e.g., annual meetings of the entire research team). The plan for such meetings should be noted in the proposal/application.

**Milestone Meeting:** The PI will be required to present an update on progress toward accomplishing the goals of the award at a Milestone Meeting to be held in the National Capital Area after the conclusion of year 2 of the period of performance. The PI may bring up to three additional members of the research team to the meeting. The Milestone Meeting will be attended by members of the TBIPHRP Programmatic Panel, CDMRP staff, the USAMRAA Grants/Contracts Officer, and other DOD stakeholders.

**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 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 Department of Veterans Affairs (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 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](https://cdmrp.health.mil/pubs/pdf/Conducting%20Research%20Military%20Pop%20DoD_funded_7NOV2022.pdf).

The anticipated direct costs budgeted for the entire period of performance for an FY23 TBIPHRP FPA should not exceed **\$5.0M**. 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](#).

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.

***The CDMRP expects to allot approximately \$23.3M to fund approximately three FY23 TBIPHRP FPA proposals/applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the 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 funded with FY23 funds, which will expire for use on September 30, 2029.***

**This BAA may support applied research, preclinical research, clinical research, and clinical trials/testing (or equivalent).** FPA proposals/applications that include a clinical trial have additional proposal/application and review requirements. **This BAA may not be used to support studies requiring an exception from informed consent (EFIC).** For more information, see [Section II.D.2, Content and Form of the Proposal/Application Submission](#) and [Section II.E.1, Criteria](#).

***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. 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 the Code of Federal Regulations, Title 32, Part 219 (32 CFR 219). Funded trials are required to register the study in the National Institutes of Health (NIH) clinical trials registry, [www.clinicaltrials.gov](http://www.clinicaltrials.gov), prior to initiation of the study. Refer to the General Application Instructions, Appendix 1, Section B, for further details.

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

***Clinical research*** encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. ***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.*** Clinical research is observational in nature and includes: (1) Research that does not seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do not seek to study the safety, effectiveness, and/or efficacy outcomes of an intervention. (3) Outcomes research and health services research that do not fit under the definition of clinical trial. Excluded from the definition of clinical research are in vitro studies that utilize human tissues that cannot be linked to a living individual. **Note:** Studies that meet the requirements for exemption under [§46.104\(d\)\(4\) of the Common Rule](#) are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

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

If the proposed clinical trial involves the use of a drug that has not been approved by the U.S. 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/authorized must be secured or will be submitted to the appropriate Regulatory Agency within the first 60 days of the award must be included in the FY23 TBIPHRP FPA 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/authorized must be secured or will be submitted to the appropriate Regulatory Agency within 60 days of the award must be included in the FY23 TBIPHRP FPA 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.

**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.

**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 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](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.

**Research Involving Animals:** All research funded by the FY23 TBIPHRP FPA involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHRO Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. *Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.* Refer to the General Submission Instructions, Appendix 1, for additional information.

*If the proposed research involves more than one institution, plans for the multi-institutional structure governing the research protocol(s) should be outlined.* In addition, a written plan for single IRB review arrangements must be provided for research conducted in the United States involving more than one institution. 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 research/trials.



**Rigor of Preclinical Research Design:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 ([www.nature.com/nature/journal/v490/n7419/full/nature11556.html](http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html)). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models should describe how these standards will be addressed as part of their Research Plan (part of [Attachment 1](#), Project Narrative). Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>.

**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 FPA, inclusion of Community-Based Participatory Research (CBPR) approaches is required.* The inclusion of CBPR can be documented in [Attachment 11](#), CBPR Letters of Commitment, and [Attachment 12](#), 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 team 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 be 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.

## **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, Section III.

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

#### **II.C.1.b. Principal Investigator:**

- The PI named by the organization on the proposal/application must be an independent investigator at or above the level of Assistant Professor (or equivalent).
  - Project leaders for each of the complementary and synergistic research projects must be at or above the level of Assistant Professor (or equivalent).
  - The PI is required to devote a minimum of 20% effort to this award.

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 the SAM to verify that an organization is eligible to receive federal awards. More information about SAM is available at <https://sam.gov/SAM/>. Refer to the General Submission Instructions, Appendix 3, for additional information.

***Conflicts of Interest:*** 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 19.7, Defense Federal Acquisition Regulation Supplement (DFARS) 219.7. A mutually agreeable plan will be developed during the award negotiation process and incorporated as part of the resultant contract.

In addition to other information provided herein, by submitting an 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-proposal/pre-application or proposal/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 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). An exception, applicants may submit the research project described in their FY23 TBIPHRP Clinical Trial Award (Funding Opportunity Number HT9425-23-S-TBIHP1) applications as part of a proposal/application to the FY23 TBIPHRP FPA; 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 proposals/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 applications following pre-application submission.

**Grants.gov** is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a 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-TBIPH2.

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.

***Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.***

### **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 proposal/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 application submissions associated with them. eBRAP will validate full 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](mailto:help@eBRAP.org) or 301-682-5507 prior to the proposal/application submission deadline.

#### **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 proposal/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](mailto: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 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 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](mailto: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](mailto:help@eBRAP.org) or 301-682-5507.

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. Enter the organization’s Business Official 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 will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, 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 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 proposal/application. For questions related to panel members and pre-proposals/pre-applications or proposals/applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **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 (five-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 FPA Focus Areas](#).
- **Overarching Challenge:** Describe the unifying challenge or question to be addressed and how it is relevant to a critical problem or question in psychological health conditions and/or TBI research and/or patient care. Clearly articulate the scientific rationale for the overarching challenge, including relevant preliminary data and literature citations.
- **Specific Aims and Study Design:** The FY23 TBIPHRP FPA strongly encourages a minimum of four individual but complementary research projects addressing the overarching challenge. For each proposed project, state the hypothesis to be tested, the specific aims, and the objectives to be reached. Specific aims should be independent and not depend on the successful completion of prior aims or other research projects. Briefly describe the experimental approach. Describe how the projects are interrelated, synergistic, and align with the overarching challenge to advance a solution beyond what would be possible through individual efforts.
- **Research Team:** Briefly describe the composition, expertise, and organization of the research team. Identify the project leaders and describe their role in and commitment to the projects, with additional emphasis on the leadership role and commitment of the PI. Briefly describe how these features will facilitate the success of the key aspects of the projects.
- **Impact and Relevance to Military Health:** Describe the potential near-term and long-term impact of the proposed research on a critical problem or question in psychological health conditions and/or TBI and/or patient care. Explain how the effort is relevant to the health care needs of Service Members, Veterans, and/or military beneficiaries.
- **Clinical Trial (if applicable):** If one or more of the proposed research projects includes a clinical trial, briefly state the clinical intervention(s), subject population(s), and the type and phase of the clinical trial(s). Describe the objectives of the proposed clinical trial(s), how it addresses the overarching challenge, and how it complements the other projects.
- **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.* Provide biographical sketches for the PI and project leaders to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

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 project is relevant to at least one sub-area within one of the three [FY23 TBIPHRP FPA Focus Areas](#).
- **Overarching Challenge:** How well the unifying challenge or question addresses a critical problem or question in psychological health conditions and/or TBI research and/or patient care. How well the scientific rationale supports the overarching challenge.
- **Specific Aims and Study Design:** How well a hypothesis and specific aims are defined for each proposed project and to what extent each project's approach will address them. How well the proposed projects complement each other and synergistically address the overarching challenge to advance a solution beyond what would be possible through individual efforts.
- **Research Team:** To what degree the composition, expertise, and commitment of the PI and project leaders are appropriate with respect to their abilities to successfully complete the projects and the extent to which the PI is prepared and committed to lead the research team and proposed projects.
- **Impact and Relevance to Military Health:** Whether the proposed research will have a potential near-term and long-term impact on a critical problem or question in psychological health conditions and/or TBI research and/or patient care. To what degree the project is relevant to the health care needs of Service Members, Veterans, and/or military beneficiaries.

- **Clinical Trial (if applicable):** How well the objectives of the proposed clinical trial(s) address the overarching challenge and complement the other projects.
- **Notification of Pre-Application Screening Results**

Following the pre-proposal/pre-application screening, PIs will be notified as to whether or not 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.

*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 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 an application package consisting of PDF forms. If more than one person is entering text into an 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 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**

<b>Proposal/Application Package Location</b>
Download proposal/application package components for HT9425-23-S-TBIPH2 from Grants.gov ( <a href="https://www.grants.gov">https://www.grants.gov</a> ) 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.
<b>Full Proposal/Application Package Components</b>
<b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> 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: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a></li> </ul>
<b>Proposal/Application Package Submission</b>
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> 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 <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the proposal/application submission.</p> <p><b>Note:</b> 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 <i>prior to</i> the proposal/application submission deadline. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>
<b><a href="#">Proposal/Application Verification Period</a></b>
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 <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b>

## 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.

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 (40-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.

Describe the proposed project in detail using the outline below.

**Overall Program:** Provide a description of the comprehensive effort using the following outline. Applicants are strongly encouraged to submit a minimum of four research projects; additional studies are allowed. Emphasize areas of synergy throughout the narrative.

- **Overarching Challenge:** Describe the unifying, [overarching challenge](#) or question to be addressed and how it is relevant to a critical problem or question in psychological health conditions and/or TBI research and/or patient care. Describe



how the proposed research addresses at least one sub-area within one of the three [FY23 TBIPHRP FPA Focus Areas](#). Clearly articulate the rationale for the overarching challenge, including relevant literature citations. Clearly describe how the proposed research projects are not dependent upon each other but are interrelated and synergistic and will advance toward a solution through a multidisciplinary research program. Describe how each project will address the overarching challenge in a unique but complementary way and how the combined efforts of the projects will address the overarching challenge more effectively than if the projects were conducted independently.

- **Leadership:** Describe how the PI’s research experience, leadership skills, and commitment to making an impact in psychological health conditions and/or TBI research and/or patient care demonstrate substantial qualifications to coordinate this collaborative effort. Describe the PI’s demonstrated success in leading large, focused collaborative projects and how it will contribute to achieving the overarching goal(s) of the proposed effort. Outline the PI’s responsibilities during the conduct of the proposed research effort. *Note that these responsibilities should align with the minimum 20% PI effort required for this award.* Discuss the qualifications of the research team being brought together by the PI and how the assembled expertise will create a robust, synergistic collaboration necessary to address the overarching challenge and enable the success of the proposed research.
  
- **Implementation Plan:** Provide a detailed strategic implementation plan for completing the proposed projects that identifies critical milestones and explain how these milestones will be achieved. Outline the knowledge, expertise, and technical innovations that the investigative team will utilize to make decisions, allocate resources, and accomplish the milestones. Describe how CBPR/ stakeholder engagement will make meaningful contributions to the success of the overall program. *Full details of the CBPR approach are required for all proposals/applications and should be provided in Attachments [11](#) and [12](#).* Describe and/or provide evidence that the research can be initiated without delay once the award is made. Present an overall management plan to facilitate a consistent and intensive flow of ideas and information among all team members, including aspects such as adherence to regulatory requirements, administrative support, and oversight to accelerate translation of the projects’ outcomes to patients and/or for clinical use. Outline shared research resources and/or cores that will be created and/or leveraged throughout the research program. Describe plans for communication, data transfer among the collaborating institutions, and how data, specimens, and/or imaging products obtained during the study will be handled. If applicable, describe how Standard Operating Procedures will be created, reviewed, implemented, and modified during the course of the award. Describe how individual project performance will be assessed during the course of the award, including progression toward defined milestones, realization of study objectives, and addressing the overarching challenge. If an EAB is to be utilized, describe the role of the board and the expertise to be sought in its members. To avoid potential COIs in the review of the proposal/ application, potential candidates for an EAB should not be contacted, recruited, or named during the proposal/application process.

– **Data and Research Resources Sharing Plan**

- Describe how data and resources generated during the period of performance 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 at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-016.html>. Other National Institutes of Health (NIH)-supported data sharing resources can be found here: [https://www.nlm.nih.gov/NIHbmic/domain\\_specific\\_repositories.html](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 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.

**Research Plan:** Provide the following details for each proposed research project, organizing each project clearly and separately. ***Start each project on a separate page.***

- **Title:** Provide a title for each project.
- **Project Leader:** Identify the project leader and any key personnel, as appropriate, describing each person’s qualifications, specific contributions, and evidence of strong commitment to the project.
- **Background:** For each project, the project leader must 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 project. The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or hypotheses. If proposing translational or clinical research, it is important to describe the project



showing proof of concept and, if applicable, efficacy in an in vivo system(s) to support relevance to the intended patient population, translational feasibility, and promise of the approach. **Full details of the CBPR approach are required for all studies enrolling human subjects and should be provided in Attachments [11](#) and [12](#).** Establish the relevance and applicability of the proposed research and findings to the intent of the mechanism and at least one sub-area within one of the three [FY23 TBIPHRP FPA Focus Areas](#).

- **Objectives/Specific Aims/Hypothesis:** Provide a description of the purpose and objectives of the study with detailed specific aims and hypotheses. 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 Statement of Work (SOW; [Attachment 5](#)).
- **Environment:** Describe the research environment and the availability of and accessibility to facilities and resources (including patient populations, samples, and collaborative arrangements) that will support the research requirements.
- **Research Strategy and Feasibility:** Describe the experimental design, methods, and analyses in sufficient detail for evaluation and their relevance to the completion of the specific aims. Provide a description of how the study will be controlled and how the study variables will be measured. Explain how the research strategy will address the [overarching challenge](#) and meet appropriate milestones. Identify potential problem areas and present alternative methods and approaches to mitigate any risks that are identified. Describe how the proposed project is feasible and will be completed within the proposed performance period.

***For research involving animals:***

- When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the summary. Applicants should consult the ARRIVE 2.0 guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE 2.0 guidelines can be found at <https://arriveguidelines.org/arrive-guidelines>. The summary should address the following points for each proposed animal study:
  - Briefly describe the research objective(s) of the animal study.
  - Provide evidence that the chosen animal model(s) is validated and well justified in the literature. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and the relevance to human biology.
    - ❖ Describe approaches that will be undertaken to validate or corroborate findings from animal studies to relevant human data sources/populations. This could include, but is not limited to, validation of animal transcriptomic

data using publicly available human transcriptomic datasets, confirmation of histological findings in a human postmortem case series, and validation against fluid-based or imaging biomarkers.

- ❖ Describe how the proposed validation approaches or corroborative studies “de-risk” the possibility that the findings from the animal study cannot be translated into human populations.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA (or international equivalent) or next stage of development, if applicable.

***For research involving human subjects/samples/data:***

- Justify how the chosen human subjects/samples/datasets are appropriate for the proposed research project.
- For studies performing retrospective or prospective human subject recruitment or observation, describe the population(s) of interest and how access to the population(s) or dataset(s) will be achieved; ***full details on human subject recruitment will be required in the Human Subject Recruitment and Safety Procedures ([Attachment 8](#))***.
- Describe the availability of the proposed study population and past successes in recruiting similar populations. If active-duty military, military families, and/or Veteran population(s) or datasets will be used in the proposed research project, describe how access to the population(s)/dataset(s) will be obtained.
- If applicable, describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA (or international equivalent) or next stage of development; ***full details will be required in the Regulatory Strategy ([Attachment 10](#))***.

***For clinical trials:***

- Provide detailed plans for initiating and conducting the clinical trial during the course of this award.
- As appropriate, state the investigational product regulatory exemption (e.g., FDA IND/IDE or international equivalent) application status or approvals. ***Note that an active investigational product regulatory exemption (e.g., FDA IND/IDE) application for the proposed indication has been submitted or authorized (without clinical hold status) OR a statement and associated justification that an investigational product regulatory exemption (e.g., FDA IND/IDE ) application for the proposed indication is not required must be in the FY23 TBIPHRP FPA proposal/application (full details will be required in the Regulatory Strategy, [Attachment 10](#)).***
- Describe the type of clinical trial to be performed (e.g., treatment, prevention, diagnostic), the phase of trial and/or class of device (as appropriate), and the study model (e.g., single group, parallel, crossover). Provide preclinical and/or clinical evidence to support the safety of the intervention.
- Identify the intervention to be tested and describe the projected endpoints/outcomes. Define the primary, secondary, or interim endpoints/outcome measures, why they were chosen, and how and when they will be assessed. If the study design (e.g., selection of outcome measures) was guided by communications/interactions with the FDA or international equivalent, please describe. Outline the timing and procedures planned during the follow-up period.
- Describe the study population, and how the sample population represents the targeted patient population that might benefit from the proposed intervention. Explain the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random); ***full details will be required in the Human Subject Recruitment and Safety Procedures ([Attachment 8](#)).***
- 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 research/trial. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers). If multiple site studies are involved, state the approximate number of subjects to be enrolled at each site.
  - Outline the timing and procedures planned during the follow-up period. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.
  - Provide evidence to document the availability of and access to all critical reagents, including the intervention itself, if applicable, for the duration of the proposed clinical trial.

- Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, and statistician) possesses the appropriate expertise in conducting clinical trials; *full details will be required in the Study Personnel (Attachment 13)*.
- **Statistical Plan:** Describe the statistical model and data analysis plan with respect to the study objectives. Include a complete power analysis (including method by which it was derived) to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the proposal/application. If applicable, 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. 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.
- **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.
- **Clinical 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. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. 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 or not 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 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 that will demonstrate 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 an application submitted through an extramural organization, the 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 FPA are subject to a federal purpose license. A term of the FY23 TBIPHRP FPA 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 Management Plan (two-page limit):** If a Data Management Plan is provided within [Attachment 8](#), Human Subject Recruitment and Safety Procedures, then submission of the Data Management Plan under “Supporting Documentation” is not required. Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instruction 3200.12](#).
  - For Extramural Applications: Refer to General Submission Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.
  - For Intramural Applications: Refer to General Submission Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.
- **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 Abstracts (one-page limit per abstract): 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.

***Technical abstracts must be provided for the overall program, as well as each individual project, with the abstract for each project starting on a separate page.***



Clarity and completeness within the space limits of the technical abstract are highly important. Describe the proposed research effort of the overall project and each individual project, including the following elements:

- **Overarching Challenge:** Identify the unifying, overarching challenge or question that will be addressed by the research plan and describe how it relates to a critical problem or question in psychological health conditions and/or TBI research and/or patient care.
- **Background:** Briefly articulate the rationale for the overarching challenge and the proposed research.
- **Research Plan:** Provide a brief description of the studies proposed, including hypotheses, objectives, specific aims, model system(s), and scientific approach.
- **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 three [FY23 TBIPHRP FPA 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 Abstracts (one-page limit per abstract): 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 must be provided for the overall program, as well as each individual project, with the abstract for each project starting on a separate page.*** 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).

- Describe how the proposed research program addresses at least one sub-area within one of the three [FY23 TBIPHRP FPA Focus Areas](#).
- Clearly describe the critical problem or question to be addressed and the ultimate applicability and impact of the research.
- Describe the CBPR approach and implementation in the study.
- Include a concise overview of the effort that can be ***readily understood by readers without a background in science or medicine.***

- **Attachment 5: Statement of Work (no 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 FPA mechanism, refer to either the “*Suggested SOW Strategy Clinical Research\_Clinical Trial*” or “*Suggested SOW Strategy Generic Research*”, whichever format is most appropriate for the proposed effort, 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:

- If applicable, cross-mapping of data elements to psychological health conditions and/or TBI CDEs for human subjects research.
- 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
- **Attachment 6: Impact and Relevance to Military Health Statement (five-page limit): Upload as “Impact.pdf”.** For the overall program and for each individual projects, the Impact and Relevance to Military Health Statement must demonstrate alignment with at least one sub-area within the [FY23 TBIPHRP FPA Focus Areas](#) and should be written in a manner that will be *readily understood by readers without a background in science or medicine*.
  - ***Describe the near-term impact:*** Detail the anticipated outcomes that will be directly attributed to the results of the proposed research and describe anticipated short-term benefits for individuals.
  - ***Describe the long-term impact:*** Explain the long-range vision for implementation of the research 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 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](#), DOD components preferentially use of medical countermeasures approved by the United States Food and Drug Administration.*
  - 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 7: Transition Plan (three-page limit): Upload as “Transition.pdf”.** Provide information on the methods and strategies proposed to move the application’s product or knowledge research outcome(s) to the next phases of development and/or clinical use following the successful completion of the proposed effort. *Articulate this information for the overall effort as well as the individual projects.* Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. The transition plan should include the components listed below, as appropriate.
  - 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 by 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.
- o **Attachment 8: Human Subject Recruitment and Safety Procedures (no page limit): If proposing multiple human subjects research projects, start each Human Subject Recruitment and Safety Procedures on a new page and clearly identify the supported project. Combine and upload as "HumSubProc.pdf". (*Attachment 8 is only applicable and required for research recruiting human subjects.*)** As applicable, 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 research/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 research/trial(s). Describe how the inclusion and exclusion criteria meet the needs of the proposed clinical research/trial(s). 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 research/trial(s). 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 research/trial(s), 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 research/trial(s). Consider psychological, legal, social, and economic risks as well as physical risks. Consider how the proposed clinical research/trial(s) 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 to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.
- **Data Management Plan:** Describe the data to be gathered and all methods used for collection, including the following:
  - **Data:** The types of data, software, or other materials to be produced
  - **Acquisition and processing:** How the data will be acquired, including the time and location of data acquisition, if scientifically pertinent. If use of existing data resources is proposed, describe the origin of the dataset. Provide an account of the standards to be used for data and metadata format and content. Explain how the data will be processed.
  - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
  - **Confidentiality:**
    - ❖ Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
    - ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DOD are eligible to review study records.
    - ❖ Address requirements for reporting sensitive information to state or local authorities.
  - **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored who will keep the data; how the 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 data will be stored, along with a

justification for the time 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 the 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 and relevance to the study objectives described. 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 9: Intervention (no page limit): If using multiple interventions, provide the information for each intervention on a new page and clearly identify the supported project(s). Combine and upload as “Intervention.pdf”. (*Attachment 9 is only applicable and required for proposals/applications proposing clinical trials.*)** The Intervention attachment 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 and how it compares with currently available interventions and/or standards of care. As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Provide evidence indicating availability 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 clinical trial.

Summarize key preclinical pharmacological findings, dosage studies, and/or other clinical studies (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 10: Regulatory Strategy: If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “Regulatory.pdf”. (Attachment 10 is only applicable and required for proposals/applications that include a clinical trial[s].)** Answer the following questions and provide supporting documentation as applicable. If more than one clinical trial is proposed, provide the below information for each trial/intervention. For the FY23 TBIPHRP FPA, evidence of investigational product regulatory exemption (e.g., Investigational New Drug [IND] or Investigational Device Exemption [IDE]) application submission, clearance or authorization has been submitted/cleared/authorized or will be submitted to the appropriate Regulatory Agency *within the first 60 days of the award* must be included in the application.
  - State the product/intervention name.

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

- Provide evidence that the product/intervention does not require regulation by a Regulatory Agency. Note that this request includes but limited to software applications, algorithms, nutraceuticals, or behavioral health interventions. ***Submissions providing “not applicable”, “none” or similar responses do not satisfy this request and may be administratively withdrawn.*** [If the clinical trial will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements.] No further information for this attachment is required.

***For products that require regulation by a Regulatory Agency:***

- For investigator-sponsored investigational product regulatory exemptions (e.g., IND, IDE) provide evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the Regulatory Agency.
- State whether the product is FDA-approved, -licensed, or -cleared and marketed in the United States. State whether the product is approved, licensed, cleared and marketed outside of in the United States.
- If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks

associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

- If the product is not currently Regulatory Agency-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the U.S. FDA or international regulatory agency has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.
- For the FY23 TBIPHRP FPA, ***evidence that a investigational product exemption application (e.g., IDE/IND) has been submitted/cleared/authorized has been secured or will be submitted to the appropriate Regulatory Agency within 60 days of the award must be included in the FY23 TBIPHRP FPA 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 the regulatory exemption application (e.g., IND/IDE) has not been submitted to the Regulatory Agency yet, indicate when the application will be submitted to the FDA, provide a timeline for obtaining the investigational product regulatory exemption within the first 60 days of award, document in the SOW ([Attachment 5](#)).
- If available, provide a copy of the communication from the Regulatory Agency indicating the investigational product regulatory exemption (e.g., IND/IDE) application is active/safe to proceed.
- If an active investigational product regulatory exemption (e.g., IND/IDE) for the investigational product is in effect but an amendment is needed to include the proposed trial, describe the type and nature of the amendment(s) ***and provide evidence of the submission within the 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.
- **Attachment 11: CBPR Letters of Commitment (two-page limit per letter): Start each document on a new page. Combine and upload as “CBPR\_letters.pdf”.** (*Attachment 11 is required for all applications.*) 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 overall program or proposed research project(s).
- **Attachment 12: 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”.** (*Attachment 12 is required for all applications.*) 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 overall program and proposed research project(s).
  - Description of the CBPR input that will be captured and how this input will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and dissemination of the research. Include a description of how CBPR effectiveness will be assessed.
  - Description of training that will be provided to both scientific researchers and community members on CBPR approaches, decision-making, and equitable participation.
  - Description of resource allocation, decision making processes, and authorship between scientific researchers and community partners (whether individuals or organizations).

- Description of dissemination activities that will share research findings with the stakeholder communities.
- **Attachment 13: Study Personnel (no page limit): Upload as “Personnel.pdf”.**
  - Discuss the qualifications and relevant experience of the research team, including each project leader, and each individual’s specific contributions are incorporated to address the overarching challenge, individual projects’ research question(s), and enable the success of the proposed project(s).
  - Describe the PI’s record of accomplishment and their ability to lead the research team to accomplish the proposed research projects.
  - Clearly state if key personnel are not receiving salary from the award. If applicable, provide assurances/letters of commitment that the unpaid personnel will contribute the required level of effort to complete the project.
  - 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 applications. 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.
- **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 National Institutes of Health 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”.
- Key Personnel Biographical Sketches (six-page limit each): Upload as “Biosketch\_LastName.pdf”.
  - Include a biographical sketch for each Project Leader.
  - 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”.
  - Include previous/current/pending support for each Project Leader.
  - 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.

**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.

### **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-proposals/pre-application and proposal/application submissions are required. The pre-proposal/pre-application and proposal/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 FPA 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 FPA. *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**

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

The anticipated direct costs budgeted for the entire period of performance should not exceed **\$5.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate.

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

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

- **Milestone Meeting:** Travel costs for the PI and up to three additional members of the research team to attend a 1-day DOD TBIPHRP Milestone Meeting to be held in the National Capital Area during the award period of performance. This meeting will be held to provide a presentation on progress. Costs associated with travel to this meeting should be included in year 3 of the budget.
- In years three and four, travel costs for the PI and up to three additional members of the research team to present project information or disseminate project results at two separate DOD-sponsored meetings (e.g., Military Health System Research Symposium). For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area.

May be requested for (not all-inclusive):

- Travel costs in support of multidisciplinary collaborations



- Starting in year two, travel costs for the PI and one investigator per research project to attend 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 FPA.
- 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 award 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**, which are of equal importance:

- **Overall Program**
  - To what extent the unifying, overarching challenge addresses a relevant critical problem or question in psychological health conditions and/or TBI research and/or patient care and addresses at least one sub-area within one of the three [FY23 TBIPHRP FPA Focus Areas](#).
  - To what extent the research projects are not dependent upon each other but are interrelated and synergistic and will advance toward a solution through a multidisciplinary research program.
- **Leadership**
  - How well the PI demonstrates research experience, leadership skills, and commitment to making an impact in psychological health conditions and/or TBI research and/or patient care.
  - To what degree the PI's experience in successfully leading large, focused collaborative projects will contribute to achieving the overarching goal(s) of the proposed effort.
  - Whether the PI's responsibilities align with the minimum 20% effort required for this award.
  - To what degree the quality and extent of organizational support are appropriate for the proposed research.
  - To what extent the qualifications of the research team being brought together by the PI and how the assembled expertise will create a robust, synergistic collaboration necessary to address the overarching challenge and enable the success of the proposed research.
- **Implementation Plan**
  - How well the proposed projects are supported by a detailed implementation plan that identifies critical milestones and outlines the knowledge, resources, and technical innovations that will be utilized to achieve the milestones.

- How well the research resources and/or cores that will be created are leveraged throughout the research program.
- To what extent the plans to assess individual project performance during the course of the award, including progression toward defined milestones, realization of study objectives, and addressing the overarching challenge are appropriate.
- How well the overall management plan will facilitate a consistent and intensive flow of ideas and information among all team members.
- How the proposed plans for communication, data transfer among the collaborating institutions, and how plans for sharing data, specimens, and/or imaging products obtained during the study are appropriate.
- To what extent the plans for creating, reviewing, implementing, and modifying Standard Operating Procedures are appropriate, if applicable.
- **Overall Impact and Relevance to Military Health**
  - To what degree the anticipated outcome(s) or knowledge/materiel product(s) will make important scientific advances and improve the understanding, prevention, assessment, and/or treatment of psychological health conditions and/or TBI.
  - To what extent the long-range vision of the proposed research will impact the field of study and/or the lives of relevant patient or community populations.
  - If applicable, to what degree the proposed materiel or knowledge product represents an improvement to currently available pharmacologic agents, non-pharmacologic interventions, devices, or clinical practice guidance devices, or clinical guidance.
  - To what degree the study identifies potential issues that might limit the impact of the proposed research and provides strategies that may be employed to overcome those issues.
  - To what extent the proposed research is responsive to the health care needs of Service Members, Veterans, and/or military beneficiaries.
- **Community-Based Participatory Research**
  - How CBPR/stakeholder engagement will make meaningful contributions to the success of the overall program.
  - 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 proposed project(s).

- 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 that 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 application identifies and describes the intended NINDS TBI and/or PhenX CDEs to be used in human subjects research.
- If applicable, how thoroughly the application justifies any instances where existing CDEs are not applicable or appropriate.

***Scored Review Criteria for Individual Proposed Research Projects:*** Research Strategy and Feasibility is 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 project and provide the basis for the study questions and/or hypotheses.
- How relevant and applicable the proposed research and findings are to the intent of the mechanism and at least one sub-area within one of the three [FY23 TBIPHRP FPA Focus Areas](#).
- How well the purpose and objectives of the study with detailed specific aims and hypotheses are described and aligned with the tasks in the SOW.
- To what extent the experimental design, methods, and analyses are relevant to the completion of the specific aims.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources (including patient populations, samples, and collaborative arrangements).
- How well the proposal/application identifies potential problem areas and presents methods and approaches to mitigate any risks that are identified.

- Whether the proposed project is feasible and will be completed within the proposed period of performance.

***For research involving animals:***

- To what extent the choice of animal model is validated and well-justified in the literature.
- How well the study explains how and why the animal species, strain, and model(s) being used can address the scientific objectives and the relevance to human biology.
- How the approaches to validate or corroborate findings from animal studies to human data sources/populations are relevant.
- If applicable, to what extent the proposed validation approaches or corroborative studies “de-risk” the possibility that the findings from the animal study cannot be translated into human populations.

***For research involving human subjects/samples/datasets:***

- To what extent the chosen human subjects/samples/datasets are appropriate for the proposed research project.
- How well plans to collect specimens and conduct laboratory evaluations are relevant to the study objectives, if applicable.
- If applicable, how well the inclusion of international sites is justified.
- Whether the proposal/application demonstrates access to the proposed study population at each site.
- To what degree the data collection instruments are appropriate to the proposed study.
- The degree to which the recruitment, screening, and retention processes for human subjects will meet the needs of the proposed clinical research/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).
- How well the inclusion and exclusion criteria and group assignment process (if applicable) meet the needs of the proposed clinical research/trial.
- Whether the strategy for the inclusion of women and minorities is appropriate to the objectives of the proposed research.
- If applicable, to what extent the distribution of the proposed enrollment or dataset on the basis of sex/gender, race, and/or ethnicity is appropriate for the proposed research.

***For clinical trials:***

- Whether the clinical trial is designed with the appropriate primary, secondary, or interim endpoints/outcome measures.
- To what degree the intervention addresses the clinical need described.
- 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 proposal/application includes key preclinical findings, dosage studies, and/or other clinical evidence (if applicable) to support the safety and stability (as appropriate) of the intervention.
- How well research procedures are clearly delineated from routine clinical procedures.
- Whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
- **Impact**
  - How the anticipated outcomes of the proposed research will provide/improve short-term benefits for individuals.
  - How significantly the long-term benefits for implementation of the research 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
- **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.
  - As appropriate, whether the proposal/application includes evidence that the IND or IDE application (or international equivalent) has submitted/cleared/authorized or will be submitted to the appropriate Regulatory Agency within the first 60 days of the award.

- How the overall regulatory strategy and product development plan that will support the planned product indication or product label change.
- 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 application identifies intellectual property ownership and demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization.
- If applicable, how the application describes an appropriate intellectual and material property plan among participating organizations.
- If applicable, how well the 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.
- **Ethical Considerations (*for research recruiting human subjects*)**
  - To what extent the proposed clinical study/trial might affect the daily lives of the individual human subjects participating in the study.
  - To what extent the population selected to participate in the study stands to benefit from the knowledge to be gained as a result of the proposed research.



- To what degree 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**
  - To what degree the statistical model and data analysis plan is suitable for the planned study.
  - How the statistical plan, including sample size and power analysis, is adequate for the study and all proposed correlative studies.
  - As applicable, how appropriate the randomization and blinding procedures for the study are, and how well any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results are described.
  - How the justification for not utilizing randomization and/or blinding is appropriate, 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**
  - To what degree the research team's qualifications and relevant experience, including each project leader, and each individual's specific contributions are incorporated to address the overarching challenge, individual projects' research question(s), and enable the success of the proposed project(s).
  - To what degree the levels of effort are appropriate for successful conduct of the proposed work.
  - If applicable, to what extent the study team composition is able to provide military-relevant subject matter expertise to the proposed research.

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

- **Budget**

- Whether the **direct costs** exceed the allowable direct costs as published in the program announcement.
- Whether the budget is appropriate for the proposed research.
- **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 FPA 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**

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants/Contracts Officer.

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 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 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.

Annual quad charts will be required.

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 (***only required for clinical research studies and clinical trials***): Enrollment reporting on the basis of sex/gender, race, and/or 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 FPA 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).

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

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. eBRAP Help Desk**

Questions related to content or submission requirements in the FY23 TBIPHRP FPA as well as questions related to the pre-proposal/pre-application or intramural proposal/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](mailto:help@eBRAP.org)

### **II.G.2. Grants.gov Contact Center**

Questions related to extramural proposal/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](mailto: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.
- [Attachment 6](#), Impact and Relevance to Military Health Statement is missing.
- [Attachment 11](#), CBPR Letters of Commitment is missing.
- [Attachment 12](#), CBPR Statement is missing.

*For proposals/applications recruiting human subjects:*

- [Attachment 8](#), Human Subject Recruitment and Safety Procedures, is missing.

*For proposals/applications proposing a clinical trial:*

- [Attachment 9](#), Intervention, is missing.
- [Attachment 10](#), Regulatory Strategy, 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 consists solely or primarily of planning, engineering, manufacturing, or formulation activities.
- Basic research is proposed.
- Proposal/application is submitted by an intramural DOD organization as the contracting organization.
- Submission of the same research project to different funding opportunities within the same program and fiscal year. Refer to [Section II.D, Proposal/Application and Submission Information](#), for exceptions.
- Proposal/application proposes a different research project than that described in the pre-proposal/pre-application.
- PI and/or project leaders do not meet the eligibility criteria.
- A clinical research/trial is proposed that requires an EFIC.
- Proposal/application does not include a CBPR approach.

- Proposal/application failed to address a unifying, overarching challenge that will be addressed by the set of research projects proposed.
- Proposal/application failed to address at least one sub-area within one of the three [FY23 TBIPHRP FPA Focus Areas](#).
- Evidence is not provided that the investigational product regulatory exemption (e.g., IND/IDE) application has been submitted/authorized/cleared or will be submitted in the first 60 days of the award.

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

#### **II.H.1.d. Withhold**

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

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

Application Components	Action	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 Abstracts: 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"	
	Impact and Relevance to Military Health Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf"	
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 8 with file name "HumSubProc.pdf" if applicable	
	Intervention: Upload as Attachment 9 with file name "Intervention.pdf" if applicable	
	Regulatory Strategy: Upload as Attachment 10 with file name "Regulatory.pdf" if applicable	
	CBPR Letters of Commitment: Upload as Attachment 11 with file name "CBPR letters.pdf" if applicable	
	CBPR Statement: Upload as Attachment 12 with file name "CBPR_PI.pdf" if applicable	
	Study Personnel: Upload as Attachment 13 with file name "Personnel.pdf"	
	Representations (extramural submissions only): Upload as Attachment 14 with file name "RequiredReps.pdf"	
	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	

Application Components	Action	Completed
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
ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting In Vivo Experiments
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
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
EAB	External Advisory Board
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
FPA	Focused Program Award
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GUID	Global Unique Identifier
HHS	U.S. Department of Health and Human Services
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
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
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 DOD and/or 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://afrii.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.amedd.army.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/research>

U.S. Air Force 59<sup>th</sup> Medical Wing

<https://www.59mdw.af.mil/>

U.S. Army Aeromedical Research Laboratory

<https://www.usaarl.army.mil/>

U.S. Army Combat Capabilities Development Command

<https://www.army.mil/devcom>



U.S. Army Institute of Surgical Research

<https://usaisr.health.mil/>

U.S. Army Medical Materiel Development Activity

<https://usamma.health.mil/>

U.S. Army Medical Research and Development Command

<https://mrhc.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), a 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

<b># Provision</b>	<b>Clause</b>
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