

I. OVERVIEW OF THE FUNDING OPPORTUNITY

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

Defense Health Program

Congressionally Directed Medical Research Programs

**Traumatic Brain Injury and Psychological Health
Research Program**

Clinical Trial Award

Announcement Type: Modified

Funding Opportunity Number: W81XWH-21-S-TBIPH1

**Catalog of Federal Domestic Assistance 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), November 1, 2021
- **Invitation to Submit a Proposal/Application:** November 5, 2021
- **Proposal/Application Submission Deadline:** 11:59 p.m. ET, December 16, 2021
- **End of Proposal/Application Verification Period:** 5:00 p.m. ET, December 21, 2021
- **Peer Review:** February 2022
- **Programmatic Review:** April 2022

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 2021 (FY21) Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP) for the Clinical Trial Award (CTA). For the remainder of the announcement, this BAA will be referenced as CTA. Specific submission information and additional administrative requirements can be found in the document titled “General Submission Instructions,” available in Grants.gov along with this BAA.

This BAA for the FY21 TBIPHRP is intended to solicit extramural research and development ideas using the authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). 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 *clinical trials 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](#).

II.A. Program Description

Proposals/applications to the FY21 TBIPHRP CTA are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by 10 USC 2358. The U.S. Army Medical Research and Development Command (USAMRDC) Congressionally Directed Medical Research Programs (CDMRP) is the execution management agent for this BAA.

In FY07, Congress appropriated funding for traumatic brain injury (TBI) and psychological health research in response to the traumatic brain injuries sustained and psychological health issues experienced by our deployed forces in Iraq and Afghanistan. The current Peer-Reviewed TBIPHRP complements ongoing Department of Defense (DOD) efforts toward promoting a better standard of care for psychological health and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. Appropriations for the TBIPHRP from FY07 through FY20 totaled \$1.872 billion (B). The FY21 appropriation is \$175 million (M).

The TBIPHRP vision is to optimize psychological health and reduce or eliminate the effects of TBI and traumatic stress. The program seeks to fund research to understand, prevent, and treat

TBI and psychological health conditions that accelerates solutions to improve the health, well-being, and healthcare of Service Members, Veterans, military beneficiaries, and the American public.

In April 2021, the TBIPHRP held a Stakeholders Meeting to engage traumatic brain injury and psychological health academic, clinical, lived experience (consumers), and government subject matter experts in an open dialogue forum to identify critical issues and underfunded areas in TBI and psychological health research and care. This meeting was attended by representatives from non-profit organizations, academia, government agencies, and the public. Outcomes from this meeting were considered by the TBIPHRP Programmatic Panel in developing the FY21 program. The FY21 Stakeholders Booklet and Meeting Summary, including presentation materials, can be found at <https://cdmrp.army.mil/tbiphrp/>.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

II.A.1. FY21 TBIPHRP CTA Focus Areas

To meet the intent of the FY21 TBIPHRP Clinical Trial Award (CTA), proposals/applications **must address at least one sub-area** within one of the three FY21 TBIPHRP CTA Focus Areas listed below. Selection of the appropriate FY21 TBIPHRP CTA Focus Area is the responsibility of the applicant.

- 1. Understand:** Research will address knowledge gaps in foundational science, epidemiology, and etiology of TBI and psychological health.
 - a. Understanding sexual harassment and assault prevention, perpetration, victimization, and response. Methodologies that ensure anonymity for participants are 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 violence are of particular interest.
 - Understanding how organizational-level factors influence interpersonal and individual conditions, choices, and behaviors as they relate to sexual assault and harassment prevention and response. Measurement and analysis of organizational-level factors, such as culture and climate, 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 and prevent retaliation. Research could include data from influencers, bystanders, and perpetrators; environmental, structural, and demographic factors (e.g., workplace culture, climate, senior leader diversity, age, gender).

- 2. Prevent:** Research will address the prevention or progression of TBI or psychological health conditions through population, selective, and indicated prevention approaches. Efforts that focus on primary prevention (including protection), screening, diagnosis, and prognosis are within scope.
- a. Identification and validation of biomarkers or other objective markers for diagnosis, prognosis, or monitoring of psychological health conditions/brain injuries, repetitive exposures, and associated sequelae (e.g., chronic migraine, dizziness, neurocognitive symptoms, sleep, post-traumatic headache). When appropriate, the use of U.S. Food and Drug Administration (FDA)-approved devices is encouraged.
 - b. Approaches or tools to prevent or mitigate brain injuries or psychological health conditions and assess health status. Research of interest includes, but is not limited to:
 - Translation of environmental sensor outputs to conditions within the brain.
 - Development of innovative materials and technologies that can prevent or mitigate 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.
 - Validated, objective methods for assessing psychological health conditions such as PTSD, adjustment disorders (AdjDs), acute stress reactions (ASRs), major depressive disorder, substance use disorders, suicidality, comorbid conditions, or TBI, and real-time health status monitoring.
 - Evidence that existing symptom-based return to activity/duty guidelines protect against risk of persistent symptoms.
 - Development of clinical decision-making frameworks or tools that incorporate objective assessments and long-term outcomes to return to activity/duty decisions.
 - Development of injury thresholds and exposure standard.
 - c. Development, evaluation, and implementation of cross-cutting 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 misuse. Examples of upstream factors could include social connectedness, inclusiveness, culture, problem-solving, emotional regulation, communication, underlying health disparities, and financial stability. Research of interest may include, but is not limited to:
 - Optimized messaging for successful dissemination and implementation.

- Inclusion of families and evaluation of impacts thereon. “Family” should be broadly defined to include not just spouses, but also parents, significant others/fiancés/partners, children, caregivers, or close friends.
- d. Solutions to increase readiness and resilience in individuals, small teams, and families 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 may be proposed.
 - Preparation of Service Members and units for missions and to help reset between deployments within the Sustainable Readiness Model¹.
 - Effective solutions to support relationships and parenting, prepare families for potential secondary trauma exposure, and empower families to access tailored support and resources. “Family” should be broadly defined to include not just spouses, but also parents, significant others/fiancés/partners, children, caregivers, or close friends.
- e. 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 healthcare 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:
- Interventions focused on sensory and locomotor dysfunction after brain injury.
 - Interventions that address cognitive functioning and reserve.
 - Personalized medicine approaches to treatment that may include tailoring treatment to the biological and endophenotypic elements present. Studies may consider how TBI, PTSD, depression, or other psychological health conditions are interrelated.
 - Rapid assessments and treatments for psychological health conditions. Interventions addressing AdjDs, ASRs, and PTSD may be proposed.

¹ https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN9412_AR525_29_FINAL.pdf

- Effective assessments and 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).
 - Considerations for sequencing and optimal combinations of pharmacologic and non-pharmacologic interventions.
- b. Treatments that promote recovery and improve long-term outcomes. Research of interest includes, but is not limited to, one or more of the following:
- Responders versus non-responders to treatment and rehabilitation.
 - Novel therapeutic candidates based on evolving changes of pathophysiology and/or theoretical mechanisms of TBI and psychological health.
 - Focus on long-term outcomes such as dementia/neurodegeneration, psychological health, family, and well-being are encouraged.
 - Interventions emphasizing community-driven participation, inclusion of caregivers/family, and education to facilitate improved functional outcomes are encouraged.
- c. Validated individual-, peer-/unit-/team-, leader-, family-, caregiver-, community-, and enterprise-level methods for reducing barriers to care for TBI or multiple mental health challenges (e.g., PTSD, suicidal ideation or behaviors, alcohol and substance use, anxiety, depression) and understanding mechanisms of change in help-seeking behavior.
- d. 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
 - Optimized messaging for successful dissemination and implementation of interventions.
 - Understanding mechanisms of action for existing evidence-based treatments is also of interest.
- e. Effective community-level postvention strategies to address social connectedness during reintegration of individuals into teams following a sexual assault or suicide event. Proposed research should prevent subsequent suicides or other counterproductive behaviors among individuals and community members.

II.B. Award Information

The intent of the FY21 TBIPHRP CTA is to support the rapid implementation of clinical trials with the potential to have a significant impact on TBI and/or psychological health through clinical applications, including healthcare products, technologies, and/or practice guidelines.

Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs or biologics), devices, therapies, clinical guidance, emerging approaches and technologies, and/or new indications for products currently FDA-approved or -cleared. Clinical trials may also be designed to evaluate novel methods for improving dissemination and implementation or investigate the mechanisms of action of new interventions.

Proposed projects may range from small proof-of-concept trials (e.g., pilot, first-in-human, phase 0) to demonstrate feasibility or inform the design of more advanced trials through large-scale trials to determine efficacy in relevant patient populations. ***Proposals/Applications proposing clinical care translation research as the primary research objective (e.g., comparative effectiveness, implementation science, healthcare services research) are not permitted under this mechanism and should consider the FY21 TBIPHRP Translational Research Award (Funding Opportunity Number: W81XWH-21-TBIPHRP-TRA).***

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 placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Funded trials are required to post a copy of the Institutional Review Board (IRB)-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in Code of Federal Regulations, Title 32, Part 219 (32 CFR 219). For more information, a Human Subject Resource Document is provided at <https://cdmrp.army.mil/pubs/pdf/Human%20Subjects%20Resource%20Document.pdf>

Clinical research is defined as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. ***Note:*** Studies that meet the requirements for IRB review Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available. ***Studies seeking to conduct clinical research only but not a clinical trial do not meet the intent of the award mechanism and will not be funded.***

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

Research Scope: The following are general descriptions, although not all-inclusive, of the scope of research projects that would be appropriate to propose under the current BAA.

Selection of the appropriate FY21 TBIPHRP CTA Research Level is the responsibility of the applicant:

- **Research Level 1:** Research Level 1 is intended to support proof-of-principle pilot studies, phase 0/small phase 1 trials, correlative studies related to an intervention, and other innovative, exploratory clinical trials. The period of performance of Research Level 1 awards will be **3** years. The anticipated *total* costs budgeted for an FY21 TBIPHRP CTA Research Level 1 award will not exceed **\$750,000**.
 - **Early-Career Investigator Partnering Option:** The FY21 TBIPHRP encourages proposals/applications that include meaningful and productive collaborations between investigators. The FY21 TBIPHRP CTA (Research Level 1 only) includes an option for an Early-Career Investigator Partnering. The Principal Investigators (PIs) may have experience in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the proposal/application. The Early-Career Investigator Partnering Option is structured to accommodate two PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with proposal/application submission. The other investigator will be the Partnering PI. ***Either the Initiating or Partnering PI may be the Early-Career Investigator.*** Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. The proposal/application is expected to describe how the PIs' unique experience/expertise combined as a partnership will better address the research question, how the unique experience/expertise that each individual brings to the proposal/application is critical for the research strategy and completion of the SOW, and why the work should be done together rather than through separate efforts. If recommended for funding, each PI will be named to an individual award within the recipient organization. For individual Department of Defense (DOD) FY21 TBIPHRP submission requirements for the Initiating and Partnering PI, refer to [Section II.D.2, Content and Form of the Proposal/Application Submission](#).
- **Research Level 2:** Research Level 2 is intended to support phase 1 and more advanced clinical trials for promising treatments or interventions. The period of performance of Research Level 2 awards will be **4** years. The anticipated *total* costs budgeted for an FY21 TBIPHRP CTA Research Level 2 award will not exceed **\$3M**.
- **Research Level 3:** Research Level 3 is intended to support larger-scale clinical trials that demonstrate efficacy in relevant patient populations. The period of performance of Research Level 3 awards will be **4** years. The anticipated *total* costs budgeted for an FY21 TBIPHRP CTA Research Level 3 award will not exceed **\$6M**.

Funding from this award mechanism must support a clinical trial and cannot be used for animal studies. PIs seeking funding for a preclinical research project or a clinical research project that does not involve a clinical trial should consider one of the other applicable FY21 TBIPHRP program announcements or BAA being offered.

If the proposed clinical trial involves the use of a drug that has not been approved by the FDA for the proposed investigational use, then an Investigational New Drug (IND) application to the FDA that meets all requirements under 21 CFR 312 may be required. It is the responsibility of the applicant to provide evidence from the IRB of record or the FDA if an IND is not required. If an IND is required, an IND without a partial or complete clinical hold status ***must be obtained by the FY21 TBIPHRP CTA proposal/application submission deadline***. The IND 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 IND application) and indication to be tested in the proposed clinical trial. For more information on IND applications, the FDA has provided guidance at <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm>.

If the investigational product is a device, then an Investigational Device Exemption (IDE) application to the FDA that meets all requirements under 21 CFR 812 may be required. It is the responsibility of the applicant to provide evidence from the IRB of record or the FDA if an IDE is not required or if the device qualifies for an abbreviated IDE. If an IDE is required, an IDE without a partial or complete clinical hold status ***must be obtained by the FY21 TBIPHRP CTA proposal/application submission deadline***. The IDE should be specific for the device (i.e., should not represent a derivative or modified version of the device described in the IDE application) and indication to be tested in the proposed clinical trial.

If the proposed clinical trial of an investigational product will be conducted at international sites, evidence that an application to the relevant national regulatory agency of the host country(ies) ***has been submitted by the FY21 TBIPHRP CTA proposal/application submission deadline*** is required.

The following are important aspects of the FY21 TBIPHRP CTA:

- The proposed clinical trial is expected to begin no later than 6 months after the award date, or 9 months after the award date for FDA-regulated studies.
- The proposed intervention(s) to be tested should offer significant potential impact for individuals affected by TBI and/or psychological health conditions.
- Inclusion of preliminary data relevant to the proposed clinical trial is required.
- The proposed clinical trial must be based on sound scientific rationale that is established through logical reasoning and critical review and analysis of the relevant literature.
- The proposal/application should include community-based organization(s)/members in the development and execution of the clinical trial.
- The proposal/application should describe the planned indication for the product label, if appropriate, and include an outline of the product development plan required to support that indication.
- The proposal/application should demonstrate availability of, and access to, a suitable patient population that will support a meaningful outcome for the study. The proposal/application

should include a discussion of how accrual goals will be achieved and how standards of care may impact the study population.

- The proposal/application should demonstrate documented availability of and access to the drug/compound, device, and/or other materials needed, as appropriate, for the proposed duration of the study. The quality and stability of the product should be documented and commensurate with current FDA manufacturing standards applicable to the type and phase of product being developed (i.e., Quality System Regulation, Good Manufacturing Practice [GMP] guidelines).
- The proposal/application should reflect the study team's experience interacting with the FDA, including previous FDA submissions, if applicable.
- The proposed clinical trial design should include clearly defined objectives and appropriate endpoints/outcome measures, and comply with current Good Clinical Practice (GCP) guidelines.
- The proposal/application should include a clearly articulated statistical analysis plan, appropriate statistical expertise on the research team, and a power analysis reflecting sample size projections that will answer the objectives of the study.
- The proposal/application should include a clearly articulated data management plan and use of an appropriate database to safeguard and maintain the integrity of the data. If FDA-regulated, the trial must use a 21 CFR 11-compliant database and appropriate data standards. For more on data standards, see <https://www.fda.gov/downloads/Drugs/Development/ApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM511237.pdf>.
- The proposal/application should include a clearly articulated safety management plan outlining how safety pharmacovigilance will be conducted, as applicable.
- The proposal/application should include a clearly articulated clinical monitoring plan outlining how the study will be monitored for GCP compliance.
- The proposal/application should include a study coordinator(s) who will guide the clinical protocol through the local IRB of record and other federal agency regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual.
- The proposal/application should include a Transition Plan (including potential funding and resources) as [Attachment 12](#) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of the FY21 TBIPHRP CTA.
- The proposal/application should clearly demonstrate strong institutional support and, if applicable, a commitment to serve as the FDA regulatory sponsor, ensuring all sponsor responsibilities described in 21 CFR 312, Subpart D, are fulfilled.

- Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219.

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

Refer to [Section II.D.6, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to [Section II.F.1, Federal Award Notices](#).

Relevance to Military Health: Relevance to the healthcare needs of Service Members, Veterans, military beneficiaries, and the American public 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 TBI and/or psychological health that has direct relevance to the health and/or readiness of Service Members, Veterans, military beneficiaries, and the American public
- 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

Applicants are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaborations between researchers at military or Veterans institutions and non-military institutions are strongly 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, Veterans, military beneficiaries, and the American public. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in [Appendix 2](#).

The CDMRP expects to allot approximately \$58.5M to fund approximately 14 Research Level 1, 12 Research Level 2, and 2 Research Level 3 FY21 TBIPHRP CTA proposals/applications. Funding of proposals/applications received is contingent upon the availability of federal funds for this program as well as the number of proposals/applications received, the quality and merit of the proposals/applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be initially funded with FY21 funds, which will expire for use on September 30, 2027.

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.

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 Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), 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

submission is *not* required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Submission Instructions, Appendix 1, Section B, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) 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.

A written plan for single IRB review arrangements must be provided for cooperative research conducted in the United States. 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. The master protocol and consent form must be reviewed by the HRPO prior to distribution to the additional sites for IRB/EC review. 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 proposal/application. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional clinical trials.

Use of DOD or VA Resources: If the proposed research involves access to military or Veteran patient populations and/or DOD or VA resources or databases, the proposal/application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Proposal/Application Submission Components](#), for detailed information. Refer to the General Submission Instructions, Appendix 1, Section C for additional information.

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. ***If the proposal/application is recommended for funding, the government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).***

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.army.mil/pubs/pdf/Conducting%20Research%20Military%20Pop%20DOD_June%202021.pdf.

Optimizing Research Impact Through Community Collaboration: Research funded by the FY21 TBIPHRP should be responsive to the needs of the traumatic brain injury and psychological health 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 FY21 TBIPHRP CTA, inclusion of Community-Based Participatory Research (CBPR) approaches is required (see Supporting Documentation, [Attachment 2](#)). Applicants must provide strong justification if CBPR approaches are not included as part of the research proposal.

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 and ownership for the research project and research results are jointly interpreted, disseminated, fed back to affected communities, and may be translated into interventions or policy. CBPR methods are critically important for community-level interventions and for 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 TBI and/or psychological health conditions.

CBPR is characterized by the equitable collaboration between community members and researcher. These collaborative relationships are often established through integrating community members into research teams as co-researchers, advisors, and consultants. Some examples for CBPR collaborations include:

- LEC: The research team includes at least one project advisor with lived TBI and/or psychological health experience who will provide advice and consultation throughout the planning and implementation of the research project. Lived experience consultants may include individuals with a traumatic brain injury or psychological health condition, their family members, or care partners.
- 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, policy makers, 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 lived experience consultants 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.

Required Data Sharing for Traumatic Brain Injury and Psychological Health Human Subjects Research: The CDMRP intends that information, data, and research resources generated under this funding opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and the public at large. For additional guidance, refer to the General Submission Instructions, Appendix 2, Section L.

For traumatic brain injury and psychological health research, the National Research Action Plan recommends the use of common data elements (CDEs) to facilitate sharing of data to promote collaboration, accelerate research, and advance knowledge on characterization, prevention, diagnosis, and treatment of traumatic brain injury and psychological health conditions.

- **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 cross-cutting impacts of interventions.
- As appropriate, the inclusion of both TBI and psychological health measures is strongly encouraged, regardless of the primary focus of the study.

- **Psychological Health Research**

- The TBIPHRP requires applicants to incorporate 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.

- **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 Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. The FITBIR Informatics System is a free resource designed to accelerate research progress by allowing the storage, re-analysis, integration, and rigorous comparison of multiple datasets. Currently,

FITBIR eligible research include all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging and genetic).

- In order to share data with 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 III](#).
 - Global Unique Identifier (GUID): FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards. FITBIR allows for de-identification and storage of data (medical imaging clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's GUID system facilitates repeated and multi-user access to data without the need to personally identify data sources. In order to generate a GUID for a subject, the following personally identifiable information (PII) ***must be collected in the proposed research:***
 - 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
- Note that this PII is never sent to the FITBIR system. PII cannot be extracted from the GUID. Information on GUID compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations can be found on the NIH website: <https://fitbir.nih.gov/content/global-unique-identifier>.*
- NINDS TBI CDEs: Research data elements must be reported using the National Institute of Neurological Disorders and Stroke (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 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 (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate costs and manpower needs that may be associated with data submission.
- FITBIR guidance and policies, as well as the considerable advantages of FITBIR participation to the researcher, are detailed at <https://fitbir.nih.gov/>.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including 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, Section B 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 so 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 proposals/applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their proposals/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: Proposal/Application submitted by a DOD organization as the contracting 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. Proposals/applications for this BAA may only be submitted by extramural organizations.

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 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.

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator:

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

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

The Early-Career Investigator must be an independent investigator within 10 years after completion of their terminal degree by the time of the proposal/application submission deadline (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is not excluded. Lapses in research time or appointments as denoted in the biographical sketch should be explained in the proposal/application.

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) and the Federal Awardee Performance and Integrity Information System (FAPIIS): 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 data from FAPIIS, a component within SAM, to verify that an organization is eligible to receive federal awards. More information about SAM and FAPIIS is available at <https://sam.gov/SAM/>. Refer to the General Submission Instructions, Appendix 3, Section A for additional information.

Conflicts of Interest: All awards must be free of conflicts of interest (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 Contracting Officer that COIs cannot be adequately managed. Refer to the General Submission Instructions, Appendix 3, Section D, 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, Section A.

Subcontracting Plan: If the resultant award is a contract that exceeds \$700,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.704, Army Federal Acquisition Regulation Supplement, Subpart 5119.704 (AFARS 5119.704), and Defense Federal Acquisition Regulation Supplement, Subpart 219.704 (DFARS 219.704). A mutually agreeable plan will be developed during the award negotiation process and incorporated as part of the resultant contract.

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

Refer to [Section II.H.1, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-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 proposals/applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative proposal(s)/

application(s). As an exception, applicants may submit the research project described in their FY21 TBIPHRP Clinical Trial Award proposal/application as part of a proposal/application to the FY21 TBIPHRP Focused Program Award (Funding Opportunity Number: W81XWH-21-S-TBIPH2); however, accepting multiple awards to support the same project will not be allowed.

II.D.1. Address to Request Proposal/Application Submission Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-proposals/pre-applications electronically through a secure connection, to view and edit the content of their pre-proposals/pre-applications and full proposals/applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

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 W81XWH-21-S-TBIPH1.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

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* (eBRAP.org or 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 Proposal/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 proposal/application submissions associated with them. eBRAP will validate full proposal/application files against the specific BAA requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. It is the applicant's responsibility to review all proposal/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 CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the proposal/application submission deadline.

Research Level 1 Early-Career Investigator Partnering Option: The Initiating PI must complete the pre-proposal/pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified of the pre-proposal/pre-application submission separately by email. *The Partnering PI must follow the link in the notification email in order to associate their full proposal/application package with that of the Initiating PI. After following the link, the Partnering PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP.* If not previously registered, the Partnering PI must register in eBRAP. A new pre-proposal/pre-application based on this research project should not be initiated by the Partnering PI. Applicants are urged to complete these steps as soon as possible. If they are not completed, the Partnering PI will not be able to view and modify their proposal/application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full proposal/application package components to eBRAP.

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

During the pre-proposal/pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full 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-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

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

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

No change in PI will be allowed after the pre-application deadline. If any other changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at 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.

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

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

- **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.

[FY21 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 CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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

- **Tab 4 – Conflicts of Interest**

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

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

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

- **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs 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 [FY21 TBIPHRP CTA Focus Areas](#).
- **Rationale:** Describe the ideas and scientific rationale on which the proposed clinical trial is based; include relevant literature citations. State the clinical intervention, subject population(s), phase of the clinical trial proposed, regulatory status, and sponsor. Briefly describe the project readiness to include the level of scientific evidence that supports the initiation of the proposed clinical trial, justification for the requested [research level](#), and the availability of and accessibility to the intervention and the proposed subject population.

- **Specific Aims and Study Design:** Concisely state the project’s hypothesis and/or objectives and specific aims. Briefly describe the experimental approach, including study design and endpoints/outcome measures.
- **Research Team:** Briefly state the qualifications of the PI(s) and key personnel to perform the clinical trial. Note any DOD or VA collaborations.
- **Impact and Relevance to Military Health:** Describe how the proposed work will have an impact on accelerating the movement of a promising intervention into clinical application. Explain how the project incorporates CBPR and is relevant to the healthcare needs of Service Members, Veterans, and/or military beneficiaries.
- **Pre-Proposal/Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-proposal/pre-application *must be uploaded as individual files* and are limited to the following:
 - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
 - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
 - **Key Personnel Biographical Sketches (six-page limit per individual):** *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and experience/expertise through education, positions, publications, and previous work accomplished.

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 FY21 TBIPHRP, pre-proposals/pre-applications will be screened based on the following criteria:

- **Focus Area:** The degree to which the proposed clinical trial is relevant to at least one sub-area within one of the three [FY21 TBIPHRP CTA Focus Areas](#).

- **Rationale:** How well the scientific rationale is supported, and how well the scientific evidence and availability of and accessibility to resources and subject population indicates that the research is appropriate for the [research level](#) requested.
 - **Specific Aims and Study Design:** How well the specific aims, study design, and experimental approach will address the hypothesis and/or reach the desired objectives.
 - **Research Team:** How the qualifications of the PI(s) and other key personnel are appropriate to successfully complete the clinical trial.
 - **Impact and Relevance to Military Health:** The degree to which the proposed clinical trial will have an impact on accelerating the movement of a promising intervention into clinical application. How well the research incorporates CBPR and is relevant to the healthcare needs of Service Members, Veterans, and/or military beneficiaries.
- **Notification of Pre-Proposal/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 by the PI or Initiating PI.

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

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

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

Extramural organizations must submit full proposals/applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the proposal/application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit a proposal/application package consisting of PDF forms. If more than one person is entering text into a proposal/application package, the **same version** of Adobe Reader software should be used by each person. Check the

version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Submission Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural proposals/applications through eBRAP may be withdrawn.

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

Table 1. Full Proposal/Application Submission Guidelines

Proposal/Application Package Location
Download proposal/application package components for W81XWH-21-S-TBIPH1 from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the proposal/application components and routing of the proposal/application package through the applicant organization for review prior to submission.
Full Proposal/Application Package Components
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Submission Instructions, Section III.A.1, for detailed information.
Descriptions of each required file can be found under Full Proposal/Application Submission Components: <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form
Proposal/Application Package Submission
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. A proposal/application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the proposal/application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the proposal/application submission.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov proposal/application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the proposal/application submission deadline. Do</p>

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

[Proposal/Application Verification Period](#)

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

Further Information

Tracking a Grants.gov Workspace Package.

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

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

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

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

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 MB, and the file size for the entire full proposal/application package may not exceed 200 MB.

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

The Project Narrative is NOT the formal clinical trial protocol. Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 6-9 described below. Failure to submit these attachments as part of the proposal/application package will result in rejection of the entire proposal/application.

Describe the proposed project in detail using the outline below.

- **Background:** Describe in detail the scientific rationale for the study and include a literature review, unpublished data, preliminary studies, and/or preclinical data that support the development of the proposed clinical trial and justifies the [research level](#) requested. If applicable, describe any stakeholder engagement that was performed and how it helped to formulate the hypothesis/objective and research strategy. Provide a summary of other relevant ongoing, planned, or completed clinical trials and describe how the proposed study differs. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable). The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the study and explain the applicability of the proposed findings to the intent of the mechanism and at least one sub-area within one of the three [FY21 TBIPHRP CTA Focus Areas](#).

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

- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study. State the specific aims and hypotheses and their relevance to the study purpose and objectives. The aims should align with the primary aims and associated tasks described in the SOW ([Attachment 5](#)).
- **Study Design:** Describe the type of study to be performed (e.g., treatment, prevention, diagnostic), the study phase or class (if applicable), and the study model (e.g., single group, parallel, crossover). Outline the proposed methodology in sufficient detail to show a clear course of action. Describe how the proposed project is feasible and will be completed within the proposed performance period.

- Identify the intervention to be tested and describe the projected results.
 - Define the primary, secondary, or interim endpoints/outcome measures, outline their appropriateness to the proposed research, and describe how and when they will be measured. Include a description of appropriate controls. If the study design (e.g., selection of outcome measures) was guided by communications/interactions with the FDA, please describe. Outline the timing and procedures planned during the follow-up period.
 - Describe the study population, criteria for inclusion/exclusion, and the methods used for recruitment/accrual of human subjects, specimens, or human-based resources.
 - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
 - Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures) and how it meets the needs of the proposed clinical trial. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
 - Outline whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.
 - If using psychometric measures, describe their reliability and validity.
 - If using herbal medicines or nutritional supplements, describe the proposed measures to ensure consistency of dosing of active ingredients.
 - Describe potential problem areas and discuss alternative methods/approaches that may be employed to overcome them. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. For phase 3 clinical trials, describe plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the proposal/application.

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

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **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 proposal/application review or funding decisions.
- **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 a proposal/application submitted through an extramural organization, the proposal/application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.

- **CBPR Letters of Commitment, if applicable (two-page limit per letter):** Provide a letter signed by each lived experience consultant 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 lived experience consultant(s) or community-based partner(s) and their relevance to the proposed research project.
- **CBPR Statement, if applicable (three-page limit):** If CBPR approaches are not utilized, provide a strong justification. Otherwise, describe the CBPR approach that will be used (e.g., LEC, partner organization, CAB, co-researcher model) and at what points CBPR will be employed in the study. The statement should also include:
 - Description of the 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.
 - Description of training that will be provided to both scientific researchers and community members on CBPR approaches, decision-making, and equitable participation.
 - Description of co-learning and capacity building activities among all partners.
 - Description of resource allocation, decision-making processes, and authorship between scientific researchers and community partners (whether individuals or organizations).
 - Description of process measures to assess the effectiveness of the chosen CBPR approach.
 - Description of dissemination activities with particular focus on feeding back the data to affected communities.
- **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 FY21 TBIPHRP CTA are subject to a federal purpose license. A term of the FY21 TBIPHRP CTA requires the recipient to grant the government all necessary and appropriate licenses, which could include licenses to background and proprietary information that have been developed at private expense. Refer to the General Submission Instructions, Appendix 2, Sections C and D, for more information about disclosure of proprietary information.

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

- **Intellectual and Material Property Plan:** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community, including the sharing of de-identified data with data repositories.

For proposals/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 proposals/applications involving psychological health 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.

In preparing requested budgets, applicants may include anticipated 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).

Refer to the General Submission Instructions, Appendix 2, Section L, for more information about CDMRP expectations for making data and research resources publicly available.

- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to military populations and/or DOD resources or databases.
- **Use of VA Resources (if applicable):** If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including 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. If appropriate, the proposal/application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the proposal/application should 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.

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

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

- **Background:** Present the ideas and rationale behind the proposed clinical research, including sufficient scientific evidence to support the proposed stage of research.
 - **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.
 - **Specific Aims:** State the specific aims of the study.
 - **Study Design:** Briefly describe the study design, including appropriate controls.
 - **Clinical Impact:** Briefly describe the potential near-term and long-term impact of the results of the proposed research on TBI and/or psychological health research, patient care, and the [FY21 TBIPHRP CTA Focus Area\(s\)](#) to be addressed.
 - **Relevance to Military Health:** Explain how the project is relevant to the healthcare needs of Service Members, Veterans, and/or military beneficiaries.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information. Do not duplicate the technical abstract.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the proposal/application review process because it addresses issues of particular interest to lived experience subject matter experts (consumers).

- Clearly describe the objectives and rationale for the proposed study and intervention in a manner that can be **readily understood by readers without a background in science or medicine.**
- State the [FY21 TBIPHRP CTA Focus Area\(s\)](#) to be addressed by the proposed project.

- Describe the problem or question to be addressed and the ultimate applicability and impact of the research.
 - How does the research improve the understanding, prevention, and/or treatment of TBI and/or psychological health conditions?
 - What are the potential clinical applications, benefits, and risks?
- Describe how the proposed project will benefit Service Members, Veterans, and/or military beneficiaries.
- **Attachment 5: Statement of Work (seven-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>. For the FY21 TBIRPHP CTA mechanism, refer to the “Suggested SOW Strategy Clinical Research” document for guidance on preparing the SOW and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within 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:

- Cross mapping of data elements to traumatic brain injury and/or psychological health CDEs.
- FITBIR-eligible research should include:
 - FITBIR investigator and study registration within the first 30 days of the award
 - Sharing of draft data collection forms with FITBIR
 - Annual FITBIR data submissions

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

- **Attachment 6: Intervention (no page limit): Upload as “Intervention.pdf”.** 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 proposed clinical trial. Summarize key preclinical findings, dosage studies, and/or other clinical evidence (if applicable) to support 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, 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) GCP compliance by an independent clinical trial monitor (or clinical research associate). The monitoring plan should describe the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the Sponsor and PI, and how they will be corrected and prevented by the clinical trial site/PI.
 - **Attachment 7: Human Subject Recruitment and Safety Procedures (no page limit): Upload as “HumSubProc.pdf”.** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
 - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts that will be made to achieve accrual and retention goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical research/trial(s), if applicable. Identify any potential barriers to accrual/retention and provide mitigation plans for addressing unanticipated delays (e.g. slow accrual, attrition). Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the

proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. *For clinical trials proposing to include military personnel, refer to the General Submission Instructions, Appendix 1, for more information.*

- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Describe how the inclusion and exclusion criteria meet the needs of the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.
- **Women and Minorities in the Study:** Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare 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 EFIC.*
 - *For the proposed study, provide a draft, in English, of the Informed Consent Form. FITBIR-eligible proposals/applications should include FITBIR consent language (see [Appendix III](#) for sample consent language).*

- ❖ Applicants must include language in informed consent documents to allow for submission of de-identified data to a repository or for secondary use/meta-analyses of the data. Provide justification if this is not possible.
- ❖ Applicants are also strongly encouraged to include language in consent forms to allow for optional passive follow-up via electronic health record.
- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
- Include information regarding the timing and location of the consent process.
- Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
- Address how privacy and time for decision-making will be provided and whether the potential human subject will be allowed to discuss the study with anyone before making a decision.
- Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
- Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. *Note:* In compliance with 10 USC 980 (<https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>), the proposal/application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial. If applicable, refer to the General Submission Instructions, Appendix 1, for more information.
- *Assent:* If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. *Note:* Some screening procedures may require a separate consent or a two-stage consent process.

- **Risks/Benefits Assessment:**
 - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is exposed to as a result of participation in the proposed clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. Consider how the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
 - **Risk management and emergency response:**
 - ❖ Appropriate to the study’s level of risk, describe how safety monitoring and reporting to the IRB and FDA (if applicable) will be managed and conducted.
 - ❖ Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
 - ❖ Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.
 - ❖ Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
 - ❖ Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
 - **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.
- **Attachment 8: Data Management (no page limit): Upload as “Data_Manage.pdf”.** The Data Management attachment should include the components listed below.
 - **Data Management:** Describe all methods used for data collection, including the following:
 - **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, the process for locking the database at study completion, and the length of time data will be stored. 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 FDA-regulated studies, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) are required.
- **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not 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.
- **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 are relevant to the study objectives (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.
- **Attachment 9: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “Regulatory.pdf”.** Address the following items and provide supporting documentation as applicable.
 - State the product/intervention name.

For products/interventions that do not require regulation by the FDA or an international regulatory agency:

- Provide confirmation that the product/intervention does not require regulation by the FDA in writing from the IRB of record or the FDA. If the proposed 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 the FDA and/or an international regulatory agency:

- For investigator-sponsored regulatory exemptions (e.g., IND, IDE, other international equivalent) provide evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States.
- If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication 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 FDA-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 FDA 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 FY21 TBIPHRP CTA, ***if an IND or IDE is required, the IND/IDE application must be submitted to the FDA prior to the FY21 TBIPHRP CTA proposal/application submission deadline.*** The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. If an IND or IDE application has already been submitted to the FDA, provide the date of submission, the application number, and a copy of the FDA letter acknowledging the submission. Clearly identify if a member of the study team holds the IND/IDE. If there are any existing cross-references in place, provide the IND/IDE application number(s) and associated sponsor(s). Provide an explanation of the status of the IND/IDE application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, on partial clinical hold). If the IND or IDE application has been placed on clinical hold or partial hold, explain the conditions that must be met for release of the hold. Provide a summary of previous meetings with the FDA on development of this product, if appropriate. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application. If the IND or IDE has not been submitted to the FDA yet, indicate when the application will be submitted to the FDA.
- If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
- If an active IND or 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 the timeline for submission. 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).
- 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 I 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 FDA meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines. Identify and address the impact of intellectual property

issues on product development and subsequent government access to products supported by this BAA.

- **Attachment 10: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as “Personnel.pdf”.** The Study Personnel and Organization attachment should include the components listed below.
 - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person’s position on the project. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate. Identify and provide justification for the inclusion of international sites, as appropriate. If applicable, identify the FDA regulatory sponsor and any external consultants or other experts who will assist with FDA 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.
 - **Study Personnel Description:** Briefly describe the composition of the study team, including roles of the individuals listed in the organizational chart on the project. Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed research. Describe relevant background and qualifications that demonstrate appropriate expertise to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, expertise in conducting clinical studies), including previous interactions with the FDA, if applicable.
 - **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is cooperative (i.e., involving more than one institution), clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead institution. A single IRB is required for all institutions located in the United States that are engaged in cooperative research. If applicable, describe how communication and data transfer between the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared.
 - **Partnership Statement (required only for proposals/applications submitted under the Research Level 1 Early-Career Investigator Partnering Option):** Provide a statement confirming that the Early-Career Investigator meets the [eligibility requirements](#) and includes (1) the completion dates of the terminal degree and last postdoctoral/fellowship position and (2) an explanation of any lapses in research time or appointments as denoted in the biographical sketch (if applicable). Describe how the partnership and combined experience/expertise of the Initiating/Partnering PI and

- Early-Career Investigator are critical for the research strategy and completion of the SOW. Explain how the partnership will better address the research question and why the work should be done together rather than through separate individual efforts. Explain how both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. Explain how funding will be balanced between both PIs, unless otherwise warranted and clearly justified.
- **Attachment 11: Questionnaires and Other Research Data Collection Instruments, if applicable (no page limit): Upload as “Data_Collection.pdf”.** The Questionnaires and Other Research Data Collection Instruments attachment should include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument:
 - Describe how the information collected is related to the objectives of the study.
 - Describe how and when the instrument(s) will be administered.
 - Describe how the instrument(s) will be adapted to the subject population, if applicable. If the adaptation results in a deviation from validated instruments, please justify.
 - **Attachment 12: Transition Plan (three-page limit): Upload as “Transition.pdf”.** Provide information on the methods and strategies proposed to move the product or knowledge outcomes of the program 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 post-award transition plan should include the components listed below, as appropriate.
 - A description of the outcomes expected upon completion of the proposed research efforts. Outcomes should be specific and measurable, and should include the intended end-user.
 - Details of the funding strategy that will be used to bring the outcomes to the next phase of development and/or delivery to market or incorporation into patient care (e.g., specific potential industry partners, specific funding opportunities to be applied).
 - A description of collaborations and other resources that will be used to provide continuity of development.

- For knowledge products², include proposed development or modification of clinical practice guidelines (CPGs) and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.
 - A brief schedule and milestones for bringing the outcomes to the next phase of development (e.g., further research, clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, approval by the FDA).
 - If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government’s ability to access such products or technologies in the future.
 - A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 13: Impact and Relevance to Military Health Statement (two-page limit): Upload as “Impact.pdf”.** This attachment should be written in a manner that will be *readily understood by readers without a background in science or medicine*.
- Identify the sample population(s) that will participate in the proposed intervention, describe how they represent the target population that might benefit from the intervention, and describe the potential impact and anticipated outcomes of the proposed clinical trial on the lives and health of the target population with regard to the [FY21 TBIPHRP CTA Focus Areas](#).
 - ***Describe the near-term impact:*** Detail the anticipated outcome(s) or knowledge/materiel product(s) that will make important scientific advances and improve the understanding, prevention, and/or treatment of TBI and/or psychological health conditions.
 - ***Describe the long-term impact:*** Explain the long-range vision for how the research will impact the field of study and/or the lives of relevant patient or community populations. Explain the anticipated long-term benefits from this research in the clinic or field. Discuss how the proposed materiel or knowledge product represents an improvement to currently available pharmacologic agents, non-pharmacological approaches, devices, or CPGs, if applicable.
 - 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.

² 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, 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.

- For implementation studies, describe how the proposed research will contribute to the implementation of evidence-based interventions, tools, policies, and guidelines (as applicable).
 - Describe potential issues that might limit the impact of the proposed research and strategies that may be employed to overcome those issues.
 - Describe how the proposed effort is responsive to the healthcare needs of Service Members, Veterans, and/or military beneficiaries.
 - If applicable, clearly articulate how the proposed research will be able to enhance readiness and recovery on the battlefield, during training, or in resource-limited environments.
 - If applicable, describe how the study team composition is able to provide military-relevant subject matter expertise to the proposed research.
 - If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest and/or patient care for TBI and/or psychological health. Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate
 - If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest and/or patient care for TBI and/or psychological health.
- **Attachment 14: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Submission Instructions, Appendix 5, Section B.
 - **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 a 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 proposals/applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this

assessment, each proposal/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”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.

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

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

Research Level 1 Early-Career Investigator Partnering Option: Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP proposal/application packages. The Initiating PI should not include budget information for Partnering PI even if they are located within the same organization. Refer to [Section II.D.6, Funding Restrictions](#), for detailed information.

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

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

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

components are missing, upload them to eBRAP before the end of the proposal/application verification period.

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

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

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

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

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

Attachments:

- **Attachment 5: Statement of Work (seven-page limit): Upload as “SOW.pdf”.** Refer to the General Submission Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.
- **Attachment 14: Representations: Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Submission Instructions, Appendix 5, Section B.
- **Attachment 15: Suggested Collaborating DOD Military Facility Budget Format: Upload as “MFBudget.pdf”.** Refer to the General Submission Instructions, Section III.A.8, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

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

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

- PI Biographical Sketch (six-page limit): Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
- Key Personnel Biographical Sketches (six-page limit each): Upload as “Biosketch_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.

Research & Related Budget: For extramural submissions, refer to the General Submission Instructions, Section III.A.5, for detailed information.

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

Research Level 1 Early-Career Investigator Partnering option: Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP proposal/application packages. The Initiating PI should not include budget information for Partnering PI even if they are located within the same organization. Refer to [Section II.D.6, Funding Restrictions](#), for detailed information.

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

Research & Related Subaward Budget Attachment(s) Form:

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Submission Instructions, Section III.A.7, for detailed information.)
- **Intramural DOD Collaborator(s):** Complete a separate DOD military budget, using Suggested Collaborating DOD Military Facility Budget Format (available for download on the eBRAP “Funding Opportunities & Forms” web page [<https://ebrap.org/eBRAP/public/Program.htm>]), and upload to Grants.gov attachment form as [Attachment 15](#). (Refer to the General Submission Instructions, Section III.A.8, for detailed information.)

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit proposals/applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit

proposals/applications through the Grants.gov portal. Verify the status of the applicant organization's Entity registration in SAM well in advance of the proposal/application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant. Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Submission Instructions, Section III.1, for more information on the transition and timing.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-proposal/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 FY21 TBIPHRP CTA requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content.

Proposal/Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all proposal/application components and ensure proper ordering as specified in the FY21 TBIPHRP CTA. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full proposal/application package must be submitted prior to the proposal/application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the proposal/application submission deadline.*** Other proposal/application components may be changed until the end of the proposal/application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the proposal/application verification period. If these components are missing, upload them to eBRAP before the end of the proposal/application verification period. After the end of the proposal/application verification period, the full proposal/application cannot be modified.

The full proposal/application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the proposal/application verification period. During the proposal/

application verification period, the full proposal/application package, *with the exception of the Project Narrative and Budget Form*, may be modified.

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

II.D.5. Intergovernmental Review

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

II.D.6. Funding Restrictions

For **Research Level 1**, the maximum period of performance is **3** years.

For **Research Level 1**, the anticipated total costs budgeted for the entire period of performance will not exceed **\$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the government exceeding **\$750,000** total costs or using an indirect cost rate exceeding the organization’s negotiated rate.

For **Research Levels 2 and 3**, the maximum period of performance is **4** years.

For **Research Level 2**, the anticipated total costs budgeted for the entire period of performance will not exceed **\$3M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the government exceeding **\$3M** total costs or using an indirect cost rate exceeding the organization’s negotiated rate.

For **Research Level 3**, the anticipated total costs budgeted for the entire period of performance will not exceed **\$6M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the government exceeding **\$6M** total costs or using an indirect cost rate exceeding the organization’s negotiated rate.

For **Research Level 1 Early-Career Investigator Partnering Option**, the maximum period of performance is **3** years. The anticipated combined total costs budgeted for the entire period of performance for both PIs’ proposals/applications will not exceed **\$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate. The combined budgeted total costs approved by the government will not exceed **\$750,000** or use an indirect cost rate exceeding each organization’s negotiated rate.

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

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

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

- Travel costs for the PI to present project information or disseminate project results at one DOD-sponsored meeting (e.g., progress review meeting, Military Health System Research Symposium) annually. For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.
- **Early Career Investigator Partnering Option:** Travel costs for the Initiating and Partnering PIs to present project information or disseminate project results at a DOD-sponsored meeting (e.g., progress review meeting, Military Health System Research Symposium) in year 2 of the award. For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all inclusive):

- 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).
- Travel in support of multidisciplinary collaborations
- Travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY21 TBIPHRP CTA.
- **Early Career Investigator Partnering Option:** Costs for the Initiating and Partnering PIs to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results from the FY21 TBIPHRP CTA.

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. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

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:

- **Impact and Relevance to Military Health**
 - How impactful the anticipated outcomes of the proposed clinical trial would be on the lives and health of the target population with regard to the [FY21 TBIPHRP CTA Focus Areas](#).
 - To what degree the anticipated outcome(s) or knowledge/materiel product(s) will make important scientific advances and improve the understanding, prevention, and/or treatment of TBI and/or psychological health conditions.
 - To what extent the long-term impact 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, devices, or CPGs.
 - To what degree the proposed research will contribute to the implementation of evidence-based interventions, tools, policies, and guidelines (as applicable).
 - 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.
 - If applicable, to what extent the proposed research will be able to enhance readiness and recovery in the battlefield, during training, or in resource-limited environments.
- **Research Strategy and Feasibility**
 - How well the scientific rationale, literature review, unpublished data, preliminary studies, and/or preclinical data support the development of the proposed clinical trial research project, provide the basis for the study questions and/or hypotheses, and justify the [research level](#) requested.

- Whether the proposed clinical trial is designed with the appropriate primary, secondary, or interim endpoints/outcome measures.
- To what extent stakeholder engagement was performed, and to what degree it helped formulate the projects hypothesis/objective and research strategy, if applicable.
- How well the proposal/application acknowledges potential problem areas and discusses alternative methods/approaches that may be employed to overcome them.
- How well the inclusion/exclusion criteria and group assignment process meet the needs of the proposed clinical trial.
- How well plans to collect specimens and conduct laboratory evaluations are relevant to the study objectives, if applicable.
- To what degree the data collection instruments are appropriate to the proposed study.
- **Intervention**
 - Whether there is evidence indicating availability of the intervention from its source for the duration of the proposed clinical trial (if applicable).
 - To what degree the intervention addresses the clinical need described.
 - How the intervention compares with currently available interventions and/or standards of care.
 - To what degree the 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.
 - Whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
 - How well research procedures are clearly delineated from routine clinical procedures.
- **Regulatory Strategy**
 - How the overall regulatory strategy and product development plan that will support the planned product indication or product label change, if applicable, are appropriate and well described.
 - Whether a member of the study team is the regulatory sponsor and holds the IND/IDE for the indication proposed indication (without partial or complete clinical hold status) OR a statement and associated justification that an FDA IND/IDE is not required, as applicable.

- For investigator-sponsored regulatory exemptions (e.g., IND, IDE, other international equivalent), whether there is evidence of appropriate institutional support and capabilities to ensure monitoring as required by the FDA.
- Whether plans to comply with current GLP, GMP, and GCP guidelines are appropriate.
- **Transition Plan**
 - Whether the outcomes expected upon completion of the proposed research are relevant, measurable, and include the intended end-user.
 - Whether the funding strategy described to bring the intervention to the phase of development and/or delivery to market or incorporation into patient care (e.g., specific industry partners, specific funding opportunities to be applied for) is reasonable and achievable.
 - Whether the proposed collaborations and other resources are appropriate 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, or approval by the FDA) are achievable.
 - Whether the risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
 - How well the proposal/application identifies intellectual property ownership, demonstrates the access to all appropriate intellectual property rights necessary for development and/or commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this BAA.
- **Human Subject Recruitment**
 - Whether the proposal/application demonstrates access to the proposed study population at each site.
 - The degree to which the recruitment and screening processes for human subjects will meet the needs of the proposed clinical trial.
 - How well the proposal/application identifies any potential barriers to accrual and provides mitigation plans for addressing unanticipated delays (e.g., slow accrual, attrition).
 - If applicable, how well the inclusion of international sites is justified.

- **Statistical Plan and Data Analysis**

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

- **Ethical Considerations**

- To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.
- Whether the population selected to participate in the trial stands to benefit from the knowledge to be gained as a result of the proposed research.
- How the level of risk to human subjects is minimized and how the safety monitoring and reporting is appropriate for the level of risk.
- To what degree privacy and confidentiality of study records are appropriately considered.
- To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- Whether the strategy for the inclusion of women and minorities is appropriate to the objectives of the study.
- Whether the distribution of the proposed enrollment on the basis of sex/gender, race, and/or ethnicity is appropriate for the proposed research.

- **Personnel and Communication**

- Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
- To what degree the study team's background and experience/expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, expertise in conducting clinical studies).
- 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) and at what points CBPR will be employed in the study are described.
- How the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
- If applicable, to what extent the study team composition is able to provide military-relevant subject matter expertise to the proposed research.
- How well the study management plan (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.
- For clinical trials that involve more than one institution, to what degree the multi-institutional structure governing the research protocol(s) across all participating institutions and regulatory submission plan are described and appropriate.
- **Partnership Statement (only applicable to Research Level 1 Early-Career Investigator Partnering Option proposals/applications)**
 - Whether the Early-Career Investigator meets the [eligibility requirements](#).
 - How the partnership and combined experience/expertise of the Initiating/Partnering PI and Early-Career Investigator are critical to the research strategy and completion of the SOW.
 - To what degree the partnership will better address the research question together rather than through separate individual efforts.
 - How well the proposal/application reflects that both PIs contribute equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project.
 - Whether funding will be balanced between both PIs or is otherwise warranted and appropriately justified.
- **Data and Research Resources Sharing Plan**
 - How 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, are described.
 - As applicable, how thoroughly the proposal/application identifies and describes the intended NINDS TBI and/or PhenX CDEs to be used.
 - If applicable, how thoroughly the proposal/application justifies any instances where existing CDEs are not applicable or appropriate.

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

- **Environment**

- To what degree the scientific environment, clinical setting, and accessibility of institutional resources support the proposed clinical trial at each participating center or institution (including collaborative arrangements).
- Whether there is evidence for appropriate institutional commitment from each participating institution.

- **Budget**

- Whether the **total** costs exceed the allowable total costs as published in the BAA.
- Whether the budget is appropriate for the proposed research.
- Whether funding will be balanced between both PIs or is otherwise warranted and appropriately justified.

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the proposal/application components influence the review.

II.E.1.b. Programmatic Review

To make funding recommendations and select the proposal(s)/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 FY21 TBIPHRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative impact and relevance to military health

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.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the FY21 TBIPHRP CTA will be provided to the PI(s) 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 200.88, 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 and/or FAR 9.104-1.

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

All proposal/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 proposal/application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY21 funds are anticipated to be made no later than September 30, 2022. Refer to the General Submission Instructions, Appendix 2, for additional award administration information.

After email notification of proposal/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, or other non-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/Contracts 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/Contracts 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, Initiating PI, or Partnering 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 organization or PI 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; DFARS, found in 48 CFR, Chapter 2; and Army Federal Acquisition Regulation Supplement (AFARS), found in 48 CFR, Chapter 51, apply to contracts resulting from this BAA.

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](#); the [General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

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.

The Award Terms and Conditions will specify if additional reporting is required.

Quarterly progress reports and quad charts will be required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the first annual 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 if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Inclusion Enrollment Reporting Requirement: Reporting the status of enrollment on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final technical report. The suggested Inclusion Enrollment Report format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

Awards resulting from the FY21 TBIPHRP CTA will incorporate 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. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Submission Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to content or submission requirements in the FY21 TBIPHRP CTA as well as questions related to the pre-proposal/pre-application or intramural proposal/application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural 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 CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the FY21 TBIPHRP CTA or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov proposal/application package. If the Grants.gov proposal/application package is updated or changed, the original version of the proposal/application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Administrative Actions

After receipt of pre-proposals/pre-applications or proposals/applications, the following administrative actions may occur:

II.H.1.a. Rejection

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

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

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

- Submission of a proposal/application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Intervention ([Attachment 6](#)) is missing.
- Human Subject Recruitment and Safety Procedures ([Attachment 7](#)) is missing.
- Data Management ([Attachment 8](#)) is missing.
- Regulatory Strategy ([Attachment 9](#)) is missing.
- Preclinical and/or animal research is proposed.

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 FY21 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 FY21 TBIPHRP Programmatic Panel members can be found at <https://cdmrp.army.mil/tbiphrp/panels/panels21>.*
- 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 proposals/applications. For FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Proposals/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 submitted by an intramural DOD organization as the contracting organization.
- Application proposes clinical care translation research as the primary research objective (e.g., comparative effectiveness, implementation science, healthcare services research).
- The invited proposal/application proposes a different research project than that described in the pre-proposal/pre-application.
- The proposed research is not a clinical trial.
- The PI(s) do not meet the eligibility criteria.
- **Early-Career Investigator Partnering Option:** Failure to submit both (Initiating and Partnering PI) proposals/applications by the deadline.
- Application proposes animal research.
- Submission of the same research project to different funding opportunities within the same program and fiscal year. [Refer to Section II.D, Application and Submission Information](#), for exceptions.
- Application failed to address at least one sub-area within one of the three [FY21 TBIPHRP CTA Focus Areas](#).

II.H.1.d. Withhold

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

II.H.2. Proposal/Application Submission Checklist

Proposal/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 Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Intervention: Upload as Attachment 6 with file name "Intervention.pdf"	
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 7 with file name "HumSubProc.pdf"	
	Data Management: Upload as Attachment 8 with file name "Data_Manage.pdf"	
	Regulatory Strategy: Upload as Attachment 9 with the file name "Regulatory.pdf"	
	Study Personnel and Organization: Upload as Attachment 10 with file name "Personnel.pdf"	
	Questionnaires and Other Research Data Collection Instruments: Upload as Attachment 11 with file name "Data_Collection.pdf" if applicable	
	Transition Plan: Upload as Attachment 12 with file name "Transition.pdf"	
	Impact and Relevance to Military Health Statement: Upload as Attachment 13 with file name "Impact.pdf"	
	Representations (extramural submissions only): Upload as Attachment 14 with file name "RequiredReps.pdf" if applicable	
	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	

Proposal/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
AdjDs	Adjustment Disorders
AFARS	Army Federal Acquisition Regulation Supplement
ASRs	Acute Stress Reactions
B	Billion
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
CTA	Clinical Trial Award
DFARS	Defense Federal Acquisition Regulation Supplement
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
EFIC	Exception from Informed Consent
EO	Executive Order
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FFRDC	Federally Funded Research and Development Center
FITBIR	Federal Interagency Traumatic Brain Injury Research
FY	Fiscal Year
GUID	Global Unique Identifier
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRPO	Human Research Protection Office
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
KRL	Knowledge Readiness Level
LAR	Legally Authorized Representative

M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
NPC	Non-Profit Corporation
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PH/TBIRP	Psychological Health and Traumatic Brain Injury Research Program
PI	Principal Investigator
PII	Personally Identifiable Information
PTSD	Posttraumatic Stress Disorder
RDT&E	Research, Development, Test, and Evaluation
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

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

Air Force Office of Scientific Research
<https://www.wpafb.af.mil/afri/afosr/>

Air Force Research Laboratory
<https://www.wpafb.af.mil/afri/>

Armed Forces Radiobiology Research Institute
<https://afri.usuhs.edu/home>

Combat Casualty Care Research Program
<https://ccc.amedd.army.mil>

Congressionally Directed Medical Research Programs
<https://cdmrp.army.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.amedd.army.mil>

Military Operational Medicine Research Program
<https://momrp.amedd.army.mil>

Naval Health Research Center
<https://www.med.navy.mil/Naval-Medical-Research-Center/Naval-Health-Research-Center/>

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/Naval-Medical-Research-Center/>

Office of Naval Research
<https://www.onr.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>

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

Traumatic Brain Injury Center of Excellence
<https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Research-and-Development/Traumatic-Brain-Injury-Center-of-Excellence/Research>

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

U.S. Air Force 59th 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/ccdc>

U.S. Army Institute of Surgical Research
<https://usaisr.amedd.army.mil>

U.S. Army Medical Materiel Development
Activity
<https://www.usamma.army.mil/>

U.S. Army Medical Research and
Development Command
<https://mrdc.amedd.army.mil/>

U.S. Army Medical Research Institute of
Infectious Diseases
<https://www.usamriid.army.mil/>

U.S. Army Research Institute of
Environmental Medicine
<https://www.usariem.army.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.amedd.army.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://www.wrair.army.mil>

APPENDIX III: 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 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, which can 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 on-line 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), part of the U.S. Department of Health and Human Services (HHS), an agency of the U.S. Government.

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 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, 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 if there were 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, with FITBIR being 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 identifying information related to the data they provide, 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 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 (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, 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.