I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Traumatic Brain Injury and Psychological Health Research Program

Investigator-Initiated Research Award

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-TBIPHRP-IIRA

**Assistance Listing Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 8, 2023

- **Application Submission Deadline:** 11:59 p.m. ET, July 6, 2023

- **End of Application Verification Period:** 5:00 p.m. ET, July 11 2023

- **Peer Review:** September 2023

- **Programmatic Review:** December 2023

This program announcement must be read in conjunction with the General Application Instructions, version 803. The General Application Instructions document is 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

II.A. Program Description

Applications to the Fiscal Year 2023 (FY23) Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC).

In FY07, Congress appropriated funding for traumatic brain injury (TBI) and psychological health research in response to the TBIs sustained and psychological health issues experienced by our deployed forces in Iraq and Afghanistan. The TBIPHRP complements ongoing Department of Defense (DOD) efforts toward promoting a better standard of care for TBI and psychological health in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. Appropriations for the TBIPHRP from FY07 through FY22 totaled $2.222 billion. The FY23 appropriation is $175 million (M).

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

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

II.A.1. FY23 TBIPHRP IIRA Focus Areas

To meet the intent of the FY23 TBIPHRP Investigator-Initiated Research Award (IIRA), applications ***must address at least one sub-area (1a, 1b, 2a, 2b, etc.)*** within one of the three FY23 TBIPHRP IIRA Focus Areas listed below. Bulleted items are provided to indicate additional context regarding programmatic intent but not required to be specifically addressed by applications. ***Proposed research must be hypothesis driven and can be aligned with TBI, psychological health, or both.*** Applications consisting solely or primarily of planning, engineering, manufacturing, or formulation activities may be administratively withdrawn. Selection of the appropriate FY23 TBIPHRP IIRA Focus Area and sub-area is the responsibility of the applicant.

Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns may result in application withdrawal. This includes, but is not limited to, research involving directed energy (e.g., photonic, radio frequency, acoustic energy, other non-kinetic

sources), Anomalous Health Incidents, Havana Syndrome, and associated neurological syndromes/injuries. Refer to the General Application Instructions Appendix 2, Section E.

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

    a. Understanding of risk, protective, and biological factors contributing to an individual's vulnerability to, response to, and long-term outcomes of psychological health conditions and/or TBI. Studies with an objective biomarker component are allowed. Research of interest includes, but is not limited to:

    - Understanding psychological health trajectories associated with trauma (e.g., acute stress reactions [ASRs], adjustment disorders, posttraumatic stress disorder [PTSD]) and suicidality that incorporate internal and external factors. For example, factors could include time course, demographic characteristics, career progression, history of trauma exposure, and community and cultural factors.

    - Understanding how the approach to psychiatric diagnosis (e.g., ASRs, adjustment disorders, PTSD) in the military relates to occupational impairment and/or military separation.

    - Understanding the role of genetics, endophenotypes, health demographics, previous injuries or repetitive exposures, psychological health conditions, pathophysiology, and environmental factors (e.g., extreme temperatures/pressures) on TBI.

    - Understanding the contribution of pre- and post-injury patient, family,[1] and caregiver education, as well as cultural, demographic, stigma, and bias factors that may relate to treatment-seeking and adherence.

    - Development and analysis of modeling from clinical data and other human data (e.g., electronic health records, exposure, training, and/or occupational data) to forecast the long-term and/or late effects of brain exposures, such as TBI, and co-occurring conditions.

    - Development and analysis of communication and tools/technology adoption that would facilitate clinical translation and identification of risk factors, educational barriers, social determinates of health, and other factors that may impede clinical translation.

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

    - Understanding processes of shame, stigma, and institutional betrayal among sexual assault victims and their units/teams and evaluation of approaches to mitigate these

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

experiences. Experiences of marginalized groups, male victims, and victims of intimate partner and family violence are of particular interest.

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

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

- Understanding the psychological health consequences of intimate partner and family violence.

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

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

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

      - Evaluation of environmental sensor data in aspects related to brain health and risk from brain blast and impact exposures.

      - Development of innovative materials and technologies that can prevent or reduce risk of TBI.

      - Generation of physiological evidence regarding the safety, efficacy, and utility of candidate neuroprotective measures. Animal models, if used, should be validated and well justified within the literature and should demonstrate clear alignment to clinical populations.

      - Validation of objective tools/methods for assessing and real-time health status monitoring of psychological health conditions and/or TBI.

- Development of clinical decision-making frameworks or tools that incorporate objective assessments and long-term outcomes to return to activity/duty decisions.

c. Development of injury thresholds and exposure standards for TBI.

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

- Optimized messaging for successful dissemination and implementation.

- Inclusion of families and evaluation of family impact.

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

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

- Effective pharmacologic or non-pharmacologic prevention interventions. Solutions for prevention of ASRs and PTSD or adjustment disorders may be proposed.

- Preparation of Service Members and units for missions and to help reset and improve resilience between deployments.

- Effective solutions to support relationships and parenting, prepare families for potential secondary trauma exposure, and empower families to access tailored support and resources.

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

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

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

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

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

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

- Interventions that address neurodegenerative processes associated with TBI.

- Interventions that restore cognitive reserve and functioning.

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

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

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

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

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

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

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

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

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

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

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

II.A.2. Award History

The TBIPHRP IIRA mechanism was first offered in FY21. Since then, 183 IIRA applications have been received, and 28 have been recommended for funding.

II.B. Award Information

The FY23 TBIPHRP IIRA is intended to support studies that will make an important contribution toward understanding, preventing, assessing, and treating psychological health conditions and/or TBI. Research projects may focus on applied research through translational research, including preclinical studies in animal models and human subjects, as well as correlative studies associated with an existing clinical trial.

Applications should clearly demonstrate the project's potential near-term and long-term outcome(s)/product(s) (knowledge and/or materiel) and how they will impact a critical problem or question in the field of research and/or patient care in the FY23 TBIPHRP IIRA Focus Areas(s) addressed. Research involving human subjects and human anatomical substances is permitted; *however, this FY23 TBIPHRP IIRA may not be used to conduct clinical trials.*

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

Applications proposing clinical trials may be submitted to the following FY23 TBIPHRP funding opportunities:

- Clinical Trial Award (Funding Opportunity Number HT9425-23-S-TBIPH1)

- Focused Program Award (Funding Opportunity Number HT9425-23-S-TBIPH2)

- Translational Research Award (Funding Opportunity Number HT9425-23-TBIPHRP-TRA)

- Health Services Research Award (Funding Opportunity Number HT9425-23-TBIPHRP-HSRA)

Clinical research encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. ***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.*** Clinical research is observational in nature and includes: (1) Research that does <u>not</u> seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
(2) Epidemiologic and behavioral studies that do not seek to study the safety, effectiveness, and/or efficacy outcomes of an intervention. (3) Outcomes research and health services research that do not fit under the definition of clinical trial. Excluded from the definition of clinical research are in vitro studies that utilize human tissues that cannot be linked to a living individual. *Note:* Studies that meet the requirements for exemption under [§46.104(d)(4) of the Common Rule](link) are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

For more information on how to distinguish clinical research from clinical trials, see the [Human Subject Resource Document](link).

Awards may not be used to support fundamental basic research. For this announcement, basic research is defined as research directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward process or products in mind.

If animal models are proposed, consider the following:

- Pairing clinical populations to animal models in order to validate the clinical relevance and development of prevention, assessment, and treatment solutions is encouraged.

- Proposed animal models should be well-justified, supported within the literature, and clearly align with clinical relevance.

Preliminary data are required. The rationale for a research idea may be derived from a laboratory discovery, population-based studies, a clinician's firsthand knowledge of patients, or anecdotal data. Applications must include relevant data that support the rationale and feasibly for the proposed study. These data may be unpublished or from published literature. Any unpublished, preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or members of the research team.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local Inquiry Review Board (IRB) or

Ethics Committee (EC) review. Local IRB/EC approval at the time of application submission is *not* required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of *all required and complete* documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHRO web page (https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo) for additional information.

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

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

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

Rigor of Preclinical Research Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit Attachment 8, Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines.

Data Sharing Requirement for Traumatic Brain Injury or Psychological Health Human Subjects: The CDMRP intends that information, data, and research resources generated under

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

- **All Prospective Human Subject Research**

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

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

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

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

- **Psychological Health Research**

  ○ The *TBIPHRP requires applicants to incorporate Common Data Elements (CDEs) appropriate to each field of study, such as the PhenX Core and Specialty collections*, which are available in the Mental Health Research, Substance Abuse and Addiction, and Research Domains Collections of the PhenX Toolkit, into all studies involving human subjects as applicable. Justification is required if the recommended measure in the PhenX Toolkit is not selected.

  ○ The TBIPHRP recommends that applicants consider the National Institute of Mental Health (NIMH) Data Archive (NDA) as a data sharing repository for psychological health human subjects data. The NDA provides an infrastructure for sharing research data, tools, methods, and analyses enabling collaborative science and discovery. The NDA mission is to accelerate scientific research and discovery through data sharing, data harmonization, and the reporting of research results. Consult the NDA website at https://nda.nih.gov/ for additional information.

  ○ In order to share data with the NDA, these elements *must be included* in the proposed research:

    – Updated informed consent language that includes NDA data sharing. Sample consent language can be found in Appendix 3.

    – NDA Global Unique Identifier (GUID): The NDA GUID is a subject ID that allows researchers to share data specific to a study participant without exposing personally identifiable information (PII) and makes it possible to match participants across laboratories and research data repositories. In order to generate an NDA GUID for a

subject, the following PII *must be collected in the proposed research* (this PII is never sent to the NDA):

- Complete legal given (first) name of subject at birth

- Complete legal additional name of subject at birth (if subject has a middle name)

- Complete legal family (last) name of subject at birth

- Day of birth

- Month of birth

- Year of birth

- Name of city/municipality in which subject was born

- [Sex at birth](#)

– In addition, for research participants aged 18 or over, the following data must be collected. *The expectation to collect these data does not preclude the use of other data collection instruments that collect similar data*.

- Age

- [DSM-5 crosscutting assessment (adult)](#)

- [WHODAS 2.0](#)

- [Patient Health Questionnaire - 9](#)

- [GAD - 7](#)

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

- **Traumatic Brain Injury Research**

  o The TBIPHRP *requires* that awardees make TBI research data generated by this award mechanism available to the research community through the FITBIR Informatics System. The FITBIR Informatics System is a free resource designed to accelerate research progress by allowing the storage, reanalysis, integration, and rigorous comparison of multiple datasets. Currently, FITBIR-eligible research includes all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging and genetic). Consult the NDA website at https://fitbir.nih.gov for additional information.

- o In order to share data with the FITBIR, these elements ***must be included*** in the proposed research:

  - – Updated informed consent language that includes FITBIR data sharing. Sample consent language is included in <u>Appendix 4</u>.

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

    - ▪ Complete legal given (first) name of subject at birth

    - ▪ Complete legal additional name of subject at birth (if subject has a middle name)

    - ▪ Complete legal family (last) name of subject at birth

    - ▪ Day of birth

    - ▪ Month of birth

    - ▪ Year of birth

    - ▪ Name of city/municipality in which subject was born

    - ▪ Country of birth

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

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

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

  o Applicants proposing to conduct research collecting both TBI and psychological health human subject data may follow the guidance for either TBI research, psychological health research, or both as appropriate. Applicants are recommended to justify their choice.

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

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

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

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

- Collaboration with DOD or Department of Veterans Affairs (VA) investigators or consultants

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

Use of DOD or VA Resources: If the proposed research involves access to VA or DOD patient populations, resources, or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information. ***Note, the CDMRP will not serve as the government sponsor or signatory on any access applications or agreements for DOD or VA patient populations, resources, or databases.***

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

proposed research involves a non-DOD or non-VA investigator collaborating with the DOD and/or VA.

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

Optimizing Research Impact Through Community Collaboration: Research funded by the FY23 TBIPHRP should be responsive to the psychological health conditions and/or TBI needs of the lived experience, family, and care provider communities. Through the establishment and utilization of effective and equitable collaborations and partnerships, the translational and impact potential of the proposed research can be maximized. ***For the FY23 TBIPHRP IIRA, inclusion of Community-Based Participatory Research (CBPR) approaches is encouraged, particularly for studies involving human subjects, but not required.*** The inclusion of CBPR can be documented in Attachment 11, CBPR Letters of Commitment, and Attachment 12, CBPR Statement, if applicable.

CBPR supports collaborative research that involves scientific researchers and community members working together to address diseases and conditions, particularly those that disproportionately affect health disparity populations. Recognizing the strength of each partner, scientific researchers and community members ***collaborate and contribute equitably their expertise on all aspects of the project, which may include a needs assessment, planning, research intervention design, implementation, evaluation, and dissemination***. CBPR features shared responsibility for and ownership of the research project, and the research results are jointly interpreted, disseminated, and fed back to affected communities and may be translated into interventions or policy. CBPR methods are critically important for community-level interventions and conditions affecting health disparity populations. CBPR methods, such as Lived Experience Consultation (LEC), can also have important impacts on translational research and prototype development to identify and augment the potential impact of a research program on people living with psychological health conditions and/or TBI.

CBPR collaborative relationships are often established through integrating community members into research teams as co-researchers, advisors, and consultants. ***CBPR team members cannot be employees of any of the organizations participating in the application.*** Some examples of CBPR collaborations include:

- LEC: The research team includes at least one member with lived psychological health conditions and/or TBI experience who will provide advice and consultation throughout the planning and implementation of the research project. LECs may include individuals with a TBI or psychological health condition, their family members, or care partners. Ideally an LEC should an individual(s) nominated by a foundation or advocacy group in order to represent the diversity of those with TBI or psychological health conditions, vs. individual experiences.

- Partnership with a community-based organization: The research team establishes partnerships with at least one community-based organization that provides advice and consultation throughout planning and implementation of the research project. Community-based organizations may include advocacy groups, service providers, policymakers, or other formal organizational stakeholders.

- Community advisory board (CAB): A CAB is composed of multiple community stakeholders and can take many forms, from a board of LECs to a coalition of community-based organizations or any combination thereof. As with LEC and organizational partners, the CAB provides advice and consultation throughout planning and implementation of the research project.

Additional information on CBPR can be found here:

- Chung B, Jones L, Dixon EL, et al. 2010. [Using a community partnered participatory research approach to implement a randomized controlled trial: Planning the design of community partners in care](#). *Journal of Health Care for the Poor and Underserved* 21(3):780-795. doi: 10.1353/hpu.0.0345.

- Wallerstein N and Duran B. 2010. [Community-based participatory research contributions to intervention research: The intersection of science and practice to improve health equity](#). *American Journal of Public Health* 100(S1):S40-S46. doi: 10.2105/AJPH.2009.184036.

- Patient-Centered Outcomes Research Institute's Engagement Tool and Resource Repository, https://www.pcori.org/engagement/engagement-resources/Engagement-Tool-Resource-Repository.

- Toolkit to Better Understand and Measure Stakeholder Engagement, https://icdr.acl.gov/resources/reports/getting-most-out-stakeholder-engagement-toolkit-better-understand-and-measure.

Early-Career Investigator Partnering Option: The FY23 TBIPHRP encourages applications that include meaningful and productive collaborations between investigators. The FY23 TBIPHRP IIRA includes an Early-Career Investigator Partnering Option that is structured to accommodate two PIs, one of whom is an Early-Career Investigator. The PIs may have experience in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application. One PI will be identified as the Initiating PI and will be responsible for most of the administrative tasks associated with application submission. The other investigator will be the Partnering PI. *One of the named PIs on an application submitted under the Early-Career Investigator Partnering Option must be an Early-Career Investigator who may be either the Initiating or Partnering PI*. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. The 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 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 organizations. For individual submission requirements for the Initiating and Partnering PI, refer to [Section II.D.2, Content and Form of the Application Submission](#).

The types of awards made under the program announcement will be assistance agreements. An assistance 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. The level of involvement on the part of the DOD during project performance is the key factor in determining whether to award 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, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY23 TBIPHRP IIRA should not exceed **$500,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

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

The CDMRP expects to allot approximately $10.9M to fund approximately 14 IIRA applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

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

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

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

II.C.1.b. Principal Investigator

Independent investigators at all academic/career levels (or equivalent) may be named by organizations as the PI on the application. ***Postdoctoral fellows are not considered independent investigators unless documentation is provided by the applicant's organization***.

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 application submission deadline (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is not excluded. ***Postdoctoral fellows are not considered independent investigators unless documentation is provided by the applicant's organization.*** Lapses in research time or appointments as denoted in the biographical sketch should be explained in the application. For Early-Career Investigator Partnering Option applications, at least one of the named PIs ***must*** be an Early-Career Investigator.

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

The CDMRP strongly 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.

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

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns may result in application withdrawal. This includes, but is not limited to, research involving directed energy (e.g., photonic, radio frequency, acoustic energy, other non-kinetic sources), Anomalous Health Incidents, Havana Syndrome, and associated neurological syndromes/injuries. Refer to the General Application Instructions Appendix 2, Section E.

II.D.1. eBRAP and Grants.gov

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

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

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

Extramural Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.

- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.

- Full application packages must be accessed and submitted at eBRAP.org.

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

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

Submission is a two-step process requiring both *pre-application* (eBRAP.org) and *full 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. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to Table 1, Full Application Guidelines).

The 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-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

Early-Career Investigator Partnering Option: The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified of the pre-application submission separately by email. The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account. After associating the pre-application to their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated to their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/ Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural). If not previously registered, the Partnering PI must register in eBRAP. A new 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 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 application package components to eBRAP.

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

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

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the PI (for single PI applicants) or Initiating PI (for applicants submitting under the Early-Career Investigator Partnering Option) through eBRAP (https://eBRAP.org/).

The applicant organization and associated PI(s) identified in the pre-application should be the same as those intended for the subsequent application submission. A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal and at the discretion of the USAMRAA Grants Officer. If any changes are necessary after submission of the pre-application, the applicant must contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

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

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

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

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

It is recommended that PIs identify an Alternate Submitter in the event that assistance with 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 application.

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

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

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

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

  Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Identify the sub-area within one of the three FY23 TBIPHRP IIRA Focus Area(s) under which the application will be submitted. LOIs are not screened, are used for program planning purposes only (e.g., reviewer recruitment), and will not be reviewed during either the peer or programmatic review sessions. ***An invitation to submit is not required. Full applications may be submitted after a completed LOI pre-application submission is accepted.***

- **Tab 6 – Submit Pre-Application**

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

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

Applications will not be accepted unless a complete pre-application package (LOI) has been received and processed.

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 application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (https://grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

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

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

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

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for HT9425-23-TBIPHRP-IIRA from Grants.gov (https://grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for HT9425-23-TBIPHRP-IIRA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.

Extramural Submissions	Intramural DOD Submissions
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An 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 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 application submission. *Note:* If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID *prior to* the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package	After eBRAP has processed the full application, the organizational Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of this status and will be able to

Extramural Submissions	Intramural DOD Submissions
may be modified *with the exception of the Project Narrative and Research & Related Budget Form*.	view and modify application components in eBRAP. During the application verification period, the full application package may be modified *with the exception of the Project Narrative and Research & Related Budget Form*. Your Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.
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 Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Early-Career Investigator Partnering Option: In order to make separate awards to each PI, CDMRP requires separate full 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 application package must be submitted using the unique eBRAP log number. *Note: All associated applications (Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.*

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

  Attachments:

  Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

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

  - **Attachment 1: Project Narrative (12-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

    Describe the proposed project in detail using the outline below.

    - **Background/Rationale:** Describe in detail the scientific rationale for the study and include a literature review, unpublished data, preliminary studies, and/or preclinical data that support the development of the proposed project. The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or hypotheses. Establish the relevance and applicability of the proposed research and findings to the intent of the mechanism and address at least one *sub-area within one of the three* FY23 TBIPRP IIRA Focus Areas. If applicable, describe any CBPR/stakeholder engagement that was performed and how it helped to formulate the hypothesis/objective and research strategy.

    - **Objectives/Specific Aims/Hypothesis:** Provide a description of the purpose and objectives of the study with detailed specific aims and hypotheses. Specific aims should be independent and not depend on the successful completion of prior aims. If the proposed research project is part of a larger study, present only those tasks that the TBIPHRP IIRA would fund. The aims should align with the associated tasks described in the SOW (Attachment 5).

    - **Research Strategy and Feasibility:**

      - Identify and describe how the study design, methods, models, and analyses will meet the project's goals and milestones. Describe how the proposed project is feasible and will be completed within the proposed performance period.

- Describe the statistical model and data analysis plan with respect to the study objectives. Include a complete power analysis (including method by which it was derived) to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies.

- Address potential problem areas and pitfalls and provide alternative methods and approaches.

- If cell lines or animals are to be used, justify why the proposed cell line(s) or animal model(s) were chosen and discuss the model's clinical relevance to the human condition; *full details will be required in the Animal Research Plan ([Attachment 8](#)).*

- If proposing a correlative study, specify how the proposed project complements the existing research efforts and provides additional relevant insight beyond the initial study design.

- If human subjects, human biological samples, or datasets will be used, describe the study population and include an overview of the plan for the recruitment of human subjects or the acquisition of samples. For studies proposing recruitment of human subjects, *full details will be required in Human Subject Recruitment and Safety Procedures ([Attachment 7](#)). This award may not be used to conduct clinical trials.*

- If applicable, describe the availability of the proposed study population and past successes in recruiting similar populations. If active-duty military, military families, and/or Veteran populations or datasets will be used in the proposed research project, describe the feasibility of accessing the population(s)/dataset(s).

- If the research will support therapeutic development, describe how the data will be appropriately reported and documented to support a regulatory filing with the U.S. Food and Drug Administration (FDA) or international equivalent agency. However, *this award may not be used to conduct clinical trials.*

○ **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 application.

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

author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

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

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

–   **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether 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 (two-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 program announcement, such as those from members of Congress, do not impact application review or funding decisions.

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

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

  - **Intellectual and Material Property Plan (if applicable):** 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 period of performance will be shared with the research community, including the sharing of de-identified data with repositories. As appropriate, provide the Data and Research Resources Sharing Plan for the research project proposed. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available. Information on selecting a repository can be found at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-016.html. Other National Institutes of Health (NIH)-supported data-sharing resources can be found at https://www.nlm.nih.gov/NIHbmic/domain_specific_repositories.html.

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

  - Identify and describe the planned NINDS TBI CDEs, alignment to FITBIR data elements and forms, and timelines for integrating data to the FITBIR Informatics System.

  - For UDEs, provide a justification as to why existing CDEs are not applicable or appropriate.

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

  For applications involving psychological health human subjects research:

  - Identify 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.

- **Data Management Plan (two-page limit):** If a Data Management Plan is provided within Attachment 7, Human Subject Recruitment and Safety Procedures, then submission of the Data Management Plan under "Supporting Documentation" is not required. Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instruction 3200.12.

  - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.

- For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.

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

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

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

- ○ **Attachment 3: Technical 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.

  Technical abstracts should be written using the outline below. The technical abstract should provide an appropriate description of the project's key aspects; clarity and completeness within the space limits of the technical abstract are highly important. Describe the proposed research project, including the following elements:

  – **Background/Rationale:** Present the ideas and reasoning behind the proposed research project, including sufficient scientific evidence to support the proposed stage of research.

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

  – **Specific Aims:** State the specific aims of the proposed research project.

  – **Study Design:** Briefly describe the experimental design, including model system(s) and appropriate controls.

  – **Impact:** Identify the sub-area(s) within one of the three FY23 TBIPHRP IIRA Focus Areas addressed and, if successful, how the research project will make important contributions toward the goals of understanding, preventing, assessing, and treating psychological health conditions and/or TBI.

- **Relevance to Military Health:** Briefly describe the relevance of the proposed research project to Service Members, their Families, and Veterans.

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

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

- Describe the objectives and rationale for the proposed project in a manner that can be *readily understood by readers without a background in science or medicine.*

- If applicable, describe the CBPR approach and implementation in the study.

- Describe the ultimate applicability of the research and how it addresses at least one *sub-area within one of the three* FY23 TBIPHRP IIRA Focus Areas.

- Describe the types of patients that will be helped by the research and how it will help them.

- Describe potential clinical applications, benefits, and risks.

- Describe the projected timeline to achieve the expected patient-related outcome.

- Describe how the proposed project will impact the health and well-being of Service Members, Veterans, and/or military beneficiaries.

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

For the FY23 TBIPHRP IIRA, refer to either the "*Suggested SOW Strategy Clinical Research*" or "*Suggested SOW Strategy Generic Research*", whichever format is most appropriate for the proposed effort, and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

The SOW should state the specific aims described in the Project Narrative and include a list of major tasks and subtasks that support the completion of the stated aims, including

milestones for completing the aims during the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also include the following tasks/subtasks:

- If applicable, cross-mapping of data elements to psychological health conditions and/or TBI CDEs for human subjects research

- Including language in informed consent documents to allow for submission of de-identified data to a repository or for secondary use/meta-analysis of the data

- For FITBIR-eligible research, 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

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

- **Attachment 6: Impact and Relevance to Military Health Statement (three-page limit): Upload as "Impact.pdf".** The Impact and Relevance to Military Health Statement must demonstrate alignment with at least one sub-area within the [FY23 TBIPHRP IIRA Focus Areas](#) and should be written in a manner that will be *readily understood by readers without a background in science or medicine.*

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

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

    - Describe how the proposed effort is responsive to the health care needs of Service Members, their Families, and Veterans.

        - If applicable, clearly articulate how the proposed research is likely to enhance readiness and recovery on the battlefield, during training, or in resource-limited environments. *Note that per [DOD Instruction 6200.02](#), DOD components preferentially use of medical countermeasures approved by the United States Food and Drug Administration.*

        - If applicable, describe how the study team composition can provide military-relevant subject matter expertise to the proposed research.

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

- Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate

Attachment 7: Human Subject Recruitment and Safety Procedures (no page limit): Upload as "HumSubProc.pdf". *(Attachment 7 is only applicable and <u>required</u> for applications that propose recruitment of human subjects.)* The Human Subject Recruitment and Safety Procedures attachment should include the components listed below. For the purposes of this funding opportunity Regulatory Agency refers to the FDA or any relevant international regulatory agency unless otherwise noted.

– **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, 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 research/trials that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. ***For clinical research proposing to include military personnel, refer to the General Application Instructions, Appendix 1, for more information.***

– **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical research. Describe how the inclusion and exclusion criteria meet the needs of the proposed clinical research. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

– **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification).

- Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.

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

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

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

- *For the proposed study, provide a draft, in English, of the Informed Consent Form. Applications planning to share data with the NIH NDA and/or the FITBIR-eligible applications should include the appropriate consent language for the NDA or FITBIR. See Appendices 3 and 4 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 study.

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

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

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

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

- Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. *Note:* In compliance with 10 USC 980 (https://www.gpo.gov/

fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf), the application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical research. If applicable, refer to the General Application Instructions, Appendix 1, for more information.

- *Assent:* If minors or other populations that cannot provide informed consent are included in the proposed clinical research, 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.

- **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 clinical research. Consider psychological, legal, social, and economic risks as well as physical risks. Consider how the proposed clinical research might affect the daily lives of the individual human subjects participating in the study. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

- **Risk management and emergency response:**

  ❖ Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (e.g., 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 to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **Data Management Plan:** Provide an overview of all methods used for data collection, including the following:

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

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

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

  - **Confidentiality:**

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

    ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that DOD representatives 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 Regulatory Agency oversight, 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 a Regulatory Agency, if applicable.

- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether 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.

- **Laboratories 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 8: Animal Research Plan** *(Attachment 8 is <u>required</u> for applications that propose studies utilizing animals; five-page limit per animal study):* **Upload as "AnimRschPln.pdf".** When the proposed study involves animals, the applicant is required to submit a plan describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. Applicants should consult the ARRIVE 2.0 guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and ultimately reported. The ARRIVE 2.0 guidelines can be found at https://arriveguidelines.org/arrive-guidelines. The Animal Research Plan should address the following points for each proposed animal study:

– Briefly describe the research objective(s) of the animal study.

- Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.

  - Describe approaches that will be undertaken to validate or corroborate findings from animal studies to relevant human data sources/populations. This could include, but is not limited to, validation of animal transcriptomic data using publicly available human transcriptomic datasets, confirmation of histological findings in a human postmortem case series, and validation against fluid-based or imaging biomarkers.

  - Describe how the proposed validation approaches or corroborative studies "de-risk" the possibility that the findings from the animal study cannot be translated into human populations.

- Summarize the procedures to be conducted. Describe how the study will be controlled.

- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.

- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA (or international equivalent) or next stage of development, if applicable.

○ **Attachment 9: Study Personnel and Organization (one-page limit): Upload as "Personnel.pdf"** *(Attachment 9 is <u>required</u> for all applications)*.

  - For Single PI Option Applications

    - Discuss the qualifications and experience/expertise of the research team and each individual's specific contributions to the project, including how the appropriate experience is incorporated to address the research question and enable the success of the proposed project.

    - Clearly state if key personnel are not receiving salary from the award. If applicable, provide assurances/Letters of Commitment that the unpaid personnel will contribute the required level of effort to complete the project.

    - Describe the PI's record of accomplishment and their ability to lead the research team to accomplish the proposed research project. Describe previous experience most pertinent to this project.

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

– For Early-Career Investigator Partnering Option Applications

- Provide a statement confirming that the Early-Career Investigator meets the [eligibility requirements](). ***Postdoctoral fellows are not considered independent investigators unless documentation is provided by the applicant's organization.***

- Provide the completion dates of the terminal degree and last postdoctoral/ fellowship position.

- Provide an explanation of any lapses in research time or appointments as denoted in the biographical sketch, if applicable.

- Describe how the partnership and combined experience/expertise of both PIs are critical for the development of the research strategy and completion of the SOW.

- Explain how the partnership will better address the research question and why the work should be done together rather than through separate individual efforts.

- Explain how both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project.

- Explain how funding will be balanced between both PIs, unless otherwise warranted and clearly justified.

○ **Attachment 10: Transition Plan (three-page limit): Upload as "Transition.pdf".** Describe/discuss the methods and strategies proposed to move the intervention to the next phase of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The post-award transition plan should include the components listed below.

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

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

– For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or

modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. (A "knowledge product" is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, or tools or to support materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.) For knowledge products, include proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.

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

- – If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.

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

- ○ **Attachment 11: CBPR Letters of Commitment, if applicable (two-page limit per letter): Upload as "CBPR_letters.pdf.** Provide a letter signed by each LEC or community-based partner(s) confirming their role and commitment to participate on the research team. The letter should include the qualifications and background of the LEC(s) or community-based partner(s) and their relevance to the proposed research project.

- ○ **Attachment 12: CBPR Statement, if applicable (three-page limit): Upload as "CBPR_PI.pdf".** Provide a statement that includes:

  - – Description of the CBPR approach that will be used (e.g., LEC, partner organization, CAB, co-researcher model) and at what points it will contribute to the research project.

  - – Description of the CBPR input that will be captured and how this input will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and dissemination of the research. Include a description of how CBPR effectiveness will be assessed.

  - – Description of training that will be provided to both scientific researchers and community members on CBPR approaches, decision-making, and equitable participation.

- – Description of resource allocation, decision-making processes, and authorship between scientific researchers and community partners (whether individuals or organizations).

  - – Description of dissemination activities that will share research findings with the stakeholder communities.

- ○ **Attachment 13: 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 Application Instructions, Appendix 5, Section B, Representations.

- ○ **Attachment 14: 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 Application Instructions, Section III.A.8, for detailed information.

- • **Extramural and Intramural Applications**

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

  Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

  Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

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

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

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

- For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

- For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

○ 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".

- For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

- For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, 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.

Early-Career Investigator Partnering Option: Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI even if they are located within the same organization. Refer to** [**Section II.D.5, Funding Restrictions**], for detailed information.***

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

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

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

  ○ **Intramural DOD Collaborator(s):** Complete the "Suggested Collaborating DOD Military Facility Budget Format" and upload to Grants.gov attachment form as Attachment 14. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

Suggested DOD Military Budget Format: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. *Note:* Applicants should complete a separate military budget using "Suggested Collaborating DOD Military Facility Budget Format" (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]) (Attachment 14) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

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

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

For the Partnering PI, the Initiating PI must identify if the Partnering PI will be named on an extramural or intramural application (in accordance with the guidelines in Section II.C.1.a, Organization) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). The Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

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

- **Extramural and Intramural Applications**

  Attachments:

  ○ **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Refer to the General Application 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 13: Representations (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 Application Instructions,
  Appendix 5, Section B, Representations.

- ○ **Attachment 14: Suggested Collaborating DOD Military Facility Budget Format:
  Upload as "MFBudget.pdf".** Refer to the General Application Instructions,
  Section IV.A.4, 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: For extramural submissions (via Grants.gov) refer to
the General Application Instructions, Section III.A.3, and for intramural submissions (via
eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed
information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions
(via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for
intramural submissions (via eBRAP), refer to the General Application Instructions,
Section IV.A.3, 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".

  - – For extramural submissions, refer to the General Application Instructions,
    Section III.A.4, for detailed information.

  - – For intramural submissions, refer to the General Application Instructions,
    Section IV.A.3, for detailed information.

- ○ 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".

  - – For extramural submissions, refer to the General Application Instructions,
    Section III.A.4, for detailed information.

– For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

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

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form:

  ○ **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application 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 14. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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

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

II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. The pre-application and application

submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement 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. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. *If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.* Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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

Intramural DOD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, *with the exception of the Project Narrative and Budget Form*, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

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

II.D.5. Funding Restrictions

Single PI Option:

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

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

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

Early-Career Investigator Partnering Option:

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

- The **combined direct costs** budgeted for the entire period of performance for the Initiating PI and Partnering PI applications should not exceed **$500,000**. The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

- The applicants may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years. The duration of the period of performance for the Initiating PI and Partnering PI should be the same.

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

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

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

- Early-Career Investigator Partnering Option: In years two and three, travel costs for the Initiating and Partnering PIs to present project information or disseminate project results at DOD-sponsored meetings to be specified by the program office during award negotiations (e.g., IPR meeting or Military Health System Research Symposium).

May be requested for (not all-inclusive):

- Travel costs in support of multidisciplinary collaborations

- Starting in year two, travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/

technical meetings is to present project information or disseminate project results from the FY23 TBIPHRP IIRA.

- Early-Career Investigator Partnering Option: Starting in year two, travel costs for the Initiating and Partnering PIs to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY23 TBIPHRP IIRA.

- Costs associated with CBPR implementation

- Costs associated with data and research resource sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community):

  - Considerations

    – If recommended for funding, the government reserves the right to reduce the data/resource sharing budget request during negotiations in order to maximize funding available for research.

    – The TBIPHRP will not provide future TBIPHRP funds to preserve or share data/resources indefinitely.

  - Curation and developing supporting documentation, including formatting according to accepted community standards; de-identification; preparing metadata to foster discoverability, interpretation, and reuse; and formatting for transmission to and storage at a selected repository for long-term preservation and access.

  - Local management considerations, such as unique and specialized information infrastructure necessary to provide local management and preservation (e.g., before deposit into an established repository).

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

Must not be requested for:

- Clinical trial costs

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 Application 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 Application Instructions, Section III.A.5.***

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Strategy and Feasibility**

  ○ How well the scientific rationale and literature review, unpublished data, preliminary studies, and/or preclinical data support the development of the proposed project and provide the basis for the study questions and/or hypotheses.

  ○ How relevant and applicable the proposed research and findings are to the intent of the mechanism and at least one sub-area within one of the three FY23 TBIPHRP IIRA Focus Areas.

  ○ How well the purpose and objectives of the study, with detailed specific aims and hypotheses, are described and aligned with the tasks in the SOW.

  ○ How well the study design, methods, models, and analyses are described and will meet the project's goals and milestones.

  ○ How thoroughly the application acknowledges potential problem areas and pitfalls and provides alternative methods and approaches.

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

  For research involving animals:

  ○ To what extent the choice of animal model is validated and well-justified in the literature.

- How well the study explains how and why the animal species, strain, and model(s) being used can address the scientific objectives and the relevance to human biology.

- How the approaches to validate or corroborate findings from animal studies to human data sources/populations are relevant.

- If applicable, to what extent the proposed validation approaches or corroborative studies "de-risk" the possibility that the findings from the animal study cannot be translated into human populations.

For applications recruiting human subjects

- How well the inclusion/exclusion criteria meet the needs of the proposed clinical research.

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

- To what degree the recruitment, screening, and retention processes for human subjects will meet the needs of the proposed clinical research.

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

- If applicable, to what degree the plans to collect specimens and conduct laboratory evaluations are relevant to the study objectives.

- Whether the strategy for the inclusion of women and minorities is appropriate to the objectives of the study.

- To what degree the distribution of the proposed enrollment or dataset on the basis of sex/gender, race, and/or ethnicity is appropriate for the proposed research.

Ethical Considerations (*for research recruiting human subjects*)

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

- Whether the population selected to participate in the study 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 are 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.

- **Impact**

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

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

- **Relevance to Military Health**

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

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

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

- **Statistical Plan and Data Analysis**

  - As applicable, describe how the randomization and blinding procedures for the study are appropriate, and specify any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results.

  - If applicable, describe how the justification for not utilizing randomization and/or blinding is appropriate.

  - How the statistical model and data analysis plan, including sample size projections and power analysis, is appropriate to meet the objectives of the study and all proposed correlative studies.

- **Personnel**

  - To what degree the research team's qualifications and experience/expertise are appropriate to accomplish the proposed work.

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

  - Whether the levels of effort by the PI and other key personnel are appropriate to ensuring the success of the project.

- **Partnership** *(only applicable to Early-Career Investigator Partnering Option applications)*

  - Whether the Early-Career Investigator meets the eligibility requirements.

- ○ To what degree the partnership and combined experience/expertise of both PIs are critical to the research strategy and completion of the SOW.

- ○ To what degree the partnership will better address the research question together rather than through separate individual efforts.

- ○ How well the application reflects that both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project.

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

- **Transition Plan**

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

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

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

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

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

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

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

  - ○ If applicable, how well the application addresses any impact of intellectual property issues on product development and the government's ability to access such products or technologies in the future

- **Data and Research Resources Sharing Plan**

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

- ○ If applicable, how thoroughly the application identifies and describes the intended NINDS TBI and/or PhenX CDEs to be used in human subjects research.

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

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

- **Community-Based Participatory Research (*for applications that include [Attachment 11](#), CBPR Letters of Commitment, and [Attachment 12](#), CBPR Statement*)**

  - ○ To what extent CBPR/stakeholder engagement was performed and to what degree it helped formulate the project's hypothesis/objective and research strategy.

  - ○ To what extent the CBPR Letter(s) of Commitment describe the role and commitment of the lived experience or community-based partners on the research team.

  - ○ How well the CBPR approach that will be used (e.g., LEC, partner organization, CAB, co-researcher model) is described and at what points it will contribute to the overall program or research project.

  - ○ To what extent the CBPR input will be captured and meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and dissemination of the research.

  - ○ To what extent training that will be provided to both scientific researchers and community members on CBPR approaches, decision-making, and equitable participation.

  - ○ To what degree dissemination activities will share research findings with the stakeholder communities.

- **Budget**

  - ○ Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.

  - ○ Whether the budget is appropriate for the proposed research.

- **Environment**

  - ○ Whether the scientific environment is appropriate for the proposed research.

  - ○ How the quality and extent of organizational support are appropriate for the proposed research.

  - ○ If applicable, to what degree the intellectual and material property plan is appropriate.

- **Application Presentation**

    ○ To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers

- Relevance to the mission of the Defense Health Program and FY23 TBIPHRP, as evidenced by the following:

    ○ Adherence to the intent of the award mechanism

    ○ Program portfolio composition

    ○ Relative impact and military benefit

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in*** [***Section II.E.1.b, Programmatic Review***](#). Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess. An information paper describing the funding recommendations and review process for the award mechanisms for the FY23 TBIPHRP IIRA 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 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 application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or

debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (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 Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

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

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

Only an appointed USAMRAA Grants 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 Officer is the official authorizing document.**

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

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

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

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

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

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

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

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

- Certify that the current and pending support provided on the application is current, accurate, and complete;

- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and

- Have been made aware of the requirements under Section 223(a)(1) of this Act.

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

II.F.3. Reporting

Refer to the General Application 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 and/or more frequent reporting is required.

Annual quad charts will be required.

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

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

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

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET (closed on most U.S. federal holidays). Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

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

Email: support@grants.gov

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

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 803a. The program announcement numeric version code will match the General Application Instructions version code 803.

II.H.2. Administrative Actions

After receipt of applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application (LOI) was not submitted.

- Project Narrative exceeds page limit.

- [Attachment 6](), Impact and Relevance to Military Health Statement is missing.

- [Attachment 9](), Study Personnel and Organization is missing.

For applications involving animal research:

- [Attachment 8](), Animal Research Plan, is missing.

For applications using human subjects:

- [Attachment 7](), Human Subject Recruitment and Safety Procedures is missing.

- Project Narrative is missing.

Budget is missing.### II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

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

- The application fails to conform to this program announcement description.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY23, the identities of

the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.

- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.

- Application includes classified research information and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- Application consists solely or primarily of planning, engineering, manufacturing, or formulation activities.

- Basic research is proposed.

- A clinical trial is proposed.

- The PI(s) do not meet eligibility criteria.

- Early-Career Investigator Partnering Option: Failure to submit both (Initiating and Partnering PI) applications by the deadline.

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

- An application proposes clinical research that requires an EFIC.

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

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs 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"		
	Impact and Relevance to Military Health Statement: Upload as Attachment 6 with file name "Impact.pdf"		
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 7 with file name "HumSubProc.pdf" if applicable		
	Animal Research Plan: Upload as Attachment 8 with file name "AnimalPlan.pdf" if applicable		
	Study Personnel and Organization: Upload as Attachment 9 with file name "Personnel.pdf" if applicable		
	CBPR Letters of Commitment: Upload as Attachment 11 with file name "CBPR_letters.pdf" if applicable		

Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed
	CBPR Statement: Upload as Attachment 12 with file name "CBPR_PI.pdf" if applicable		
	Representations (extramural submissions only): Upload as Attachment 13 with file name "RequiredReps.pdf"		
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 14 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field		
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Budget **(intramural submissions only)**	Suggested DOD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed		

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ASR	Acute Stress Reaction
ARRIVE	Animal Research: Reporting *In Vivo* Experiments
CAB	Community Advisory Board
CBPR	Community-Based Participatory Research
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
EFIC	Exception from Informed Consent
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
FY	Fiscal Year
GUID	Global Unique Identifier
HHS	U.S. Department of Health and Human Services
IACUC	Institutional Animal Care and Use Committee
IIRA	Investigator-Initiated Research Award
IPR	Interim/In-Progress Review
IRB	Institutional Review Board
LAR	Legally Authorized Representative
LEC	Lived Experience Consultation (or Consultant)
LOI	Letter of Intent
M	Million
MB	Megabyte
MIPR	Military Interdepartmental Purchase Request
NDA	NIMH [National Institute of Mental Health] Data Archive
NIH	National Institutes of Health
NIMH	National Institute of Mental Health

NINDS	National Institute of Neurological Disorders and Stroke
NPC	Non-Profit Corporation
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORCID	Open Researcher and Contributor ID, Inc.
PHS	Public Health Service
PI	Principal Investigator
PII	Personally Identifiable Information
PTSD	Posttraumatic Stress Disorder
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
TBIPHRP	Traumatic Brain Injury and Psychological Health Research Program
UDE	Unique Data Element
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs

APPENDIX 2: DOD and VA WEBSITES

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

Advanced Research Projects Agency for Health
https://arpa-h.gov/

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

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

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

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

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

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

Defense Health Agency
https://health.mil/dha

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

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

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

Military Health System Research Symposium
https://mhsrs.health.mil/SitePages/Home.aspx

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

U.S. Department of Defense Sexual Assault Prevention and Response Office
https://www.sapr.mil

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

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

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

APPENDIX 3: SAMPLE NDA CONSENT LANGUAGE

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

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

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

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

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

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

APPENDIX 4: SAMPLE FITBIR CONSENT LANGUAGE

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

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

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

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

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

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

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

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

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note, however, that if an insurer or employer learns about you

and/or your child's participation and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

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

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

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

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

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

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

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

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

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

3. **Language for studies without a Certificate of their own**

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

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

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