

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**

Clinical Research Development Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-21-TBIPHRP-CRDA

**Catalog of Federal Domestic Assistance 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), September 8, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, September 30, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, October 5, 2021
- **Peer Review:** December 2021
- **Programmatic Review:** February 2022

This program announcement must be read in conjunction with the General Application Instructions, version 605. 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 2021 (FY21) 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 2358 (10 USC 2358). 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 Fiscal Year 2007 (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 current Peer-Reviewed TBIPHRP complements ongoing Department of Defense (DOD) efforts toward promoting a better standard of care for psychological health and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. Appropriations for the TBIPHRP from FY07 through FY20 totaled \$1.872 billion (B). The FY21 appropriation is \$175 million (M).

The TBIPHRP vision is to optimize psychological health and reduce or eliminate the effects of TBI and traumatic stress. The program seeks to fund research to understand, prevent, and treat TBI and psychological health conditions that accelerates solutions to improve the health, well-being, and healthcare of Service Members, Veterans, military beneficiaries, and the American public.

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

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

II.A.1. FY21 TBIPHRP CRDA Focus Areas

To meet the intent of the FY21 TBIPHRP Clinical Research Development Award (CRDA), applications **must address at least one sub-area** within one of the two FY21 TBIPHRP CRDA Focus Areas listed below. Selection of the appropriate FY21 TBIPHRP CRDA Focus Area is the responsibility of the applicant.

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

- Inclusion of families and evaluation of impacts thereon. “Family” should be broadly defined to include not just spouses, but also parents, significant others/fiancés/partners, children, caregivers, or close friends.
- d. Solutions to increase readiness and resilience in individuals, small teams, and families to ameliorate the potential negative impacts of specific military and life stressors. Research of interest includes, but is not limited to:
- Effective pharmacologic or non-pharmacologic prevention interventions. Solutions for prevention of ASRs and PTSD may be proposed.
 - Preparation of Service Members and units for missions and to help reset between deployments within the Sustainable Readiness Model¹.
 - Effective solutions to support relationships and parenting, prepare families for potential secondary trauma exposure, and empower families to access tailored support and resources. “Family” should be broadly defined to include not just spouses, but also parents, significant others/fiancés/partners, children, caregivers, or close friends.
- e. Solutions to address aspects of workplace culture and climate (e.g., leadership attitudes, group characteristics, group identification factors) that are associated with increases in harmful behaviors. Research of interest includes but is not limited to solutions to provide and incentivize positive options and substitutes for alcohol and substance use and promote pro-social behavioral norms.
- 2. Treat:** Research will address immediate and long-term treatments and improvements in systems of care, including access to and delivery of healthcare services. Treatment topics may include novel treatments and interventions, personalized medicine approaches, length and durability of treatment, rehabilitation, relapse, and relapse prevention.
- a. Interventions that promote sustained functional recovery, including interventions administered acutely, during the post-acute phase, or during the chronic phase of injury. Research of interest includes, but is not limited to:
- Interventions focused on sensory and locomotor dysfunction after brain injury.
 - Interventions that address cognitive functioning and reserve.
 - Personalized medicine approaches to treatment that may include tailoring treatment to the biological and endophenotypic elements present. Studies may consider how TBI, PTSD, depression, or other psychological health conditions are interrelated.
 - Rapid assessments and treatments for psychological health conditions. Interventions addressing AdjDs, ASRs, and PTSD may be proposed.

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

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

II.B. Award Information

The FY21 TBIPHRP CRDA is intended to support planning and development activities necessary to initiate a future clinical study with the potential to have a significant impact on TBI and/or psychological health. The future study to be developed at the conclusion of the CRDA may be clinical research or a clinical trial.

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. ***As stated in [Section II.H.2.c, Withdrawal](#), FY21 TBIPHRP CRDA applications that propose clinical research or a clinical trial in the CRDA period of performance may be administratively withdrawn.***

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

FY21 TBIPHRP CRDA recipients are expected to be ready to apply for advanced funding in the program year following completion of their CRDA and are encouraged to apply for future TBIPHRP funding through an appropriate FY23 or FY24 TBIPHRP program announcement or targeted broad agency announcement, if offered. Release of FY23 or FY24 TBIPHRP funding opportunity announcements and any subsequent awards will be contingent upon the appropriation and availability of federal funds for the program and competitive selection. Award of an FY21 TBIPHRP CRDA is in no way an assurance of funding for future TBIPHRP awards.

Implementation Research: FY21 TBIPHRP CRDA planning and development activities may support innovative approaches to identifying, understanding, and developing strategies for overcoming barriers to the adoption, adaptation, integration, scale-up and sustainability of evidence-based interventions, tools, policies, and guidelines. Conversely, there is a benefit in understanding circumstances that create a need to stop or reduce (“de-implement”) the use of interventions that are ineffective, unproven, low-value, or harmful. In addition, studies to advance dissemination and implementation research methods and measures are encouraged.

- For the purposes of the FY21 TBIPHRP CRDA, *implementation research* is defined as the scientific study of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and benefit population health.

Preliminary data are required. The FY21 TBIPHRP CRDA is a planning award and is not intended to support preclinical or clinical studies to generate preliminary data or proof-of-principle. *However, the FY21 TBIPHRP CRDA may be used to support the generation of preclinical data requested by the FDA as a condition to initiate a clinical study.* Applicants proposing such experiments should include evidence of communication with the FDA in [Attachment 2, Supporting Documentation](#). *Use of animals and human anatomical substances/data is permitted; however, this award may not be used to conduct prospectively enrolled human subject clinical trials or clinical research.*

Applicants looking to submit applications for clinical trials should apply to the FY21 TBIPHRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-21-S-TBIPH1).

Applicants seeking funding for other research studies may consider applying to the following FY21 TBIPHRP funding opportunities:

- FY21 TBIPHRP Idea Development Award (Funding Opportunity Number: W81XWH-21-TBIPHRP-IDA)
- Investigator-Initiated Research Award (Funding Opportunity Number: W81XWH-21-TBIPHRP-IIRA)
- Translational Research Award (Funding Opportunity Number: W81XWH-21-TBIPHRP-TRA)

Planning activities that may be supported by the FY21 TBIPHRP CRDA include, but are not limited to:

- Planning for appropriate regulatory approvals (for example, IRB submissions and FDA submissions such as FDA Investigational New Drug [IND]/Investigational Device Exemption [IDE] applications)
- Composing the research team and initiating collaborations (including community-based organizations and lived experience consultants) necessary for the future clinical research project
- Developing the research plan and statistical design
- Developing the clinical protocol
- Establishing access to appropriate patient populations or resources
- Developing training procedures
- Planning for potential intellectual or material property issues
- Developing a transition plan with associated resources and collaborations to continue to the next phase of research, including involvement of industry partners, if applicable
- Developing a data analysis/statistical plan and/or modeling for clinical research/trial design

- Cross mapping of data elements to TBI and/or psychological health common data elements (CDEs)
- **Note:** FY21 TBIPHRP CRDA applicants are encouraged to reference the FY21 TBIPHRP Clinical Trial Award (Funding Opportunity Number: W81XWH-21-S-TBIPH1) to become familiar with its requirements and to help direct proposed activities during the CRDA period of performance.

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

- Explanation of how the project addresses an aspect of TBI and/or psychological health that has direct relevance to the health and/or readiness of Service Members, Veterans, military beneficiaries, and the American public
- Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need
- Use of military or Veteran populations, samples, or datasets in the proposed research, if appropriate
- Collaboration with DOD or Department of Veterans Affairs (VA) investigators or consultants

Applicants are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with the DOD or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in [Appendix 2](#).

The 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 total costs budgeted for the entire period of performance for an FY21 TBIPHRP CRDA will not exceed **\$300,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

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

The CDMRP expects to allot approximately \$3M to fund approximately 10 FY21 TBIPHRP Clinical Research Development Award 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 FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

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

Optimizing Research Impact Through Community Collaboration: Research funded by the FY21 TBIPHRP should be responsive to the needs of the TBI and psychological health lived experience, family, and care provider communities. Through the establishment and utilization of effective and equitable collaborations and partnerships, the translational and impact potential of the proposed research can be maximized. For the FY21 TBIPHRP CRDA, inclusion of Community-Based Participatory Research (CBPR) approaches is encouraged but not required.

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

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

- LEC: The research team includes at least one project advisor with lived TBI and/or psychological health experience who will provide advice and consultation throughout the planning and implementation of the research project. Lived experience consultants may include individuals with a TBI or psychological health condition, their family members, or care partners.
- Partnership with a community-based organization: The research team establishes partnerships with at least one community-based organization that provides advice and consultation throughout planning and implementation of the research project. Community-based organizations may include advocacy groups, service providers, policy makers, or other formal organizational stakeholders.
- Community advisory board (CAB): A CAB is composed of multiple community stakeholders and can take many forms, from a board of lived experience consultants to a coalition of community-based organizations or any combination thereof. As with LEC and organizational partners, the CAB provides advice and consultation throughout planning and implementation of the research project.

Additional information on CBPR can be found here:

- Chung B, Jones L, Dixon EL, et al. 2010. [Using a community partnered participatory research approach to implement a randomized controlled trial: Planning the design of community partners in care.](#) *Journal of Health Care for the Poor and Underserved* 21(3):780-795. doi: 10.1353/hpu.0.0345.
- Wallerstein N and Duran B. 2010. [Community-based participatory research contributions to intervention research: The intersection of science and practice to improve health equity.](#) *American Journal of Public Health* 100(S1):S40-S46. doi: 10.2105/AJPH.2009.184036.

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

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

- **All Prospective Human Subject Research**
 - Applicants must include language in informed consent documents to allow for submission of de-identified data to a repository or for secondary use/meta-analyses of the data.
 - Applicants are also strongly encouraged to include language in consent forms to allow for optional passive follow-up via electronic health record.

- As applicable, applicants are strongly encouraged to include secondary outcomes in proposed studies to address potential cross-cutting impacts of interventions.
- As appropriate, the inclusion of both TBI and psychological health measures is strongly encouraged, regardless of the primary focus of the study.
- **Psychological Health Research**
 - The TBIPHRP requires applicants to incorporate CDEs appropriate to each field of study, such as the PhenX Core and Specialty collections, which are available in the Mental Health Research, Substance Abuse and Addiction, and Research Domains Collections of the [PhenX Toolkit](#), into all studies involving human subjects as applicable. Justification is required if the recommended measure in the PhenX Toolkit is not selected.
- **Traumatic Brain Injury Research**
 - The TBIPHRP requires that awardees make TBI research data generated by this award mechanism available to the research community through the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. The FITBIR Informatics System is a free resource designed to accelerate research progress by allowing the storage, re-analysis, integration, and rigorous comparison of multiple datasets. Currently, FITBIR-eligible research includes all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging, genetic).
 - In order to share data with FITBIR, these elements must be included in the proposed research:
 - Updated informed consent language that includes FITBIR data sharing. Sample consent language is included in [Appendix 3](#).
 - Global Unique Identifier (GUID): FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards. FITBIR allows for de-identification and storage of data (medical imaging clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR’s GUID system facilitates repeated and multi-user access to data without the need to personally identify data sources. In order to generate a GUID for a subject, the following personally identifiable information (PII) ***must be collected in the proposed research:***
 - Complete legal given (first) name of subject at birth
 - Complete legal additional name of subject at birth (if subject has a middle name)
 - Complete legal family (last) name of subject at birth
 - Day of birth
 - Month of birth

- Year of birth
- Name of city/municipality in which subject was born
- Country of birth

Note that this PII is never sent to the FITBIR system. PII cannot be extracted from the GUID. Information on GUID compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations can be found on the National Institutes of Health (NIH) website: <https://fitbir.nih.gov/content/global-unique-identifier>.

- NINDS TBI CDEs: Research data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs or entered into the FITBIR data dictionary as new, unique data elements (UDEs). For the most current version of the NINDS TBI CDEs, go to <http://www.commondataelements.ninds.nih.gov>. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR Informatics System. Use of the TBI CDEs is required as applicable in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI. Applicants are strongly required to review TBI CDEs and associated form structures during the development of the study collection methods. ***If approved CDEs are not incorporated, justification is required and subject to program approval.***
 - While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate costs and manpower needs that may be associated with data submission.
 - FITBIR guidance and policies, as well as the considerable advantages of FITBIR participation to the researcher, are detailed at <http://fitbir.nih.gov/>.

Research Involving Animals: All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC Office of Research Protections (ORP) 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. ***Only animal studies as required by the FDA for initiation of the future clinical study are allowed in the FY21 TBIPHRP CRDA.*** Use of animals and human anatomical substances/data is permitted; however, this award may not be used to conduct prospectively enrolled human subject clinical trials or clinical research

Use of DOD or VA Resources: If the proposed research involves access to military or Veteran patient populations and/or DOD or VA resources or databases, the 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.

Research Involving Human Anatomical Substances or Data: FY21 TBIPHRP CRDA may be used to support the generation of data specifically requested by the FDA as a condition to initiate a clinical study. All DOD-funded research involving new and ongoing research with human anatomical substances or human data must be reviewed and approved by the USAMRDC ORP, Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information. ***Only preclinical non-human use studies as required by the FDA for initiation of the future clinical study are allowed in the FY21 TBIPHRP CRDA.***

Planning for DOD-Funded Human Research with Military Populations: There are unique requirements and prohibitions for compensating DOD-affiliated personnel for study participation and for conducting research with military families/children and U.S. Army Special Operations Command populations. Additional information regarding conducting DOD-funded human research with military populations can be found at https://cdmrp.army.mil/pubs/pdf/Conducting%20Research%20Military%20Pop%20DOD_June%202021.pdf.

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 organization other than the DOD, and research institutes.

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: 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.

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

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

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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).

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.1. Address to Request Application Package

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

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

II.D.2. Content and Form of the 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 CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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 CDMRP 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 through eBRAP (<https://eBRAP.org/>).

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after

submission of the pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

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

It is recommended that applicants 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.

[FY21 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.

- **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 [FY21 TBIPHRP CRDA Focus Area\(s\)](#) under which the application will be submitted. LOIs 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.

- **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.

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://www.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	
<p>Download application package components for W81XWH-21-TBIPHRP-CRDA from Grants.gov (https://www.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.</p>	<p>Download application package components for W81XWH-21-TBIPHRP-CRDA from eBRAP (https://ebrap.org).</p>
Full Application Package Components	
<p>SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.</p>	<p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form 	<p>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:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>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.</p>

Extramural Submissions	Intramural DOD Submissions
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. 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.</p> <p><i>Note:</i> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>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. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>
<u>Application Verification Period</u>	
<p>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 may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> 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.</p>

Extramural Submissions	Intramural DOD Submissions
Further Information	
<p>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.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

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

- **Attachment 1: Project Narrative (10-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

– **Future Clinical Study:**

- Explain the research question to be addressed in the future clinical study and, if applicable, the intervention to be tested and its relevance to one or more of the [FY21 TBIPHRP CRDA Focus Areas](#). If an intervention will be tested, include relevant information about its source, FDA approval/review status (as applicable), availability, efficacy, dosing (if applicable), and mechanism of action (if known).
- Describe the scientific rationale for the study and include a literature review, preliminary studies, or preclinical data that led to and support the development of the future clinical study.
- Describe the hypothesis and/or objectives of the future clinical study.
- Describe the anticipated outcomes of the future clinical study and how they will provide/improve near-term benefits for individuals with TBI and/or psychological health conditions.
- Describe the anticipated target population for the future clinical study.

– **Development Plan Strategy and Feasibility:**

- Describe the work to be conducted during the FY21 TBIPHRP CRDA period of performance by clearly stating how each task is necessary for the initiation of the future clinical study.
- Where relevant, identify potential problems and potential alternative approaches.
- Describe the proposed timeline and plans to finalize the experimental design and develop the applicable clinical protocol and related documents (e.g., consent form, research data collection instruments) for the future clinical study, as applicable.
- Describe plans to develop applicable data collection/monitoring procedures, a data analysis plan, and other data collection tools and how they are appropriate for the scope of the future clinical study.
- If applicable, provide detailed plans for carrying out all necessary regulatory approvals (e.g., IRB, IND/IDE application process), including timelines, milestones, and planned interactions with the FDA.
- If applicable, describe planning for safety and clinical monitoring, including compliance with Good Clinical Practice (GCP) guidelines.
- Provide a timeline and plans for coordination of IRB submission and approval at each study site, as applicable.

- Describe the statistical support requirements (including data analysis and clinical trial design modeling) and support needed for the future clinical study.
- Describe how sample size estimates will be calculated, how a plan for statistical analyses will be developed, and how a human subjects recruitment plan, if applicable, will be formulated. Include plans to engage a statistician and other experts as appropriate.
- Describe plans establishing access to the relevant study population.
- Describe a plan to share and disseminate data and other resources created by the future clinical study with the greater research community. This should include a plan for cross mapping of data elements to TBI and/or psychological health CDEs.
- Describe any other preparatory activities that are required to enable the future clinical study will be accomplished.

For preclinical research to generate data specifically requested by the FDA:

- In [Attachment 2, Supporting Documentation](#), provide evidence that the proposed experiments are supported by communication(s) with the FDA.
- Provide a scientific rationale that supports the proposed experiments.
- Describe the aims, research design, hypotheses, methods, and their relevance to the data requested by the FDA.
- Describe the statistical plan as appropriate for the proposed research.
- Address potential problem areas and pitfalls, and provide alternative methods and approaches.

– **Personnel:**

- Describe how the background, expertise, and levels of effort of the PI and key personnel are appropriate to support successful planning and development activities necessary to initiate a future clinical study.
- Describe plans for developing the research team and obtaining any research resource or professional collaborations/expertise for the future clinical study, if applicable. If applicable, describe how military-relevant subject matter expertise will be identified and recruited.
- Include plans for training team members, as appropriate.
- Address involvement of DOD or VA clinicians and scientists, if any.

- **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.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Organizational Support (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 will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.

- **Regulatory Communications, if applicable (required for all applications that propose preclinical research):** Include any communications with the FDA or local IRB relevant to tasks to be completed in the period of performance, including any documents relevant to obtaining required IND/IDE approvals.
- **Intellectual Property:** Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for the development of an intellectual and material property agreement and a process for the identification and resolution of intellectual and material property issues among participating organizations.
 - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- **Data and Research Resources Sharing Plan:** If the application is generating data specifically requested by the FDA, provide a plan on how data and resources generated will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about CDMRP expectations for making data and research resources publicly available.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access DOD resources or databases.
- **Use of VA Resources (if applicable):** If the proposed research involves access to VA study resources and databases, and/or VA research space and equipment, VA PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information.* Use only

characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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 future proposed clinical study.
- **Clinical Question:** Describe the hypothesis and/or objective to be addressed in the future clinical study.
- **Development Plan:** Briefly describe how the work proposed during the FY21 TBIPHRP CRDA period of performance will lead to a future clinical study.
- **Impact:** Briefly describe the near- or long-term impact of the future clinical study on TBI and/or psychological health research, patient care, and the [FY21 TBIPHRP CRDA Focus Areas](#) to be addressed.
- **Relevance to Military Health:** Briefly describe the relevance of the future clinical study to Service Members, Veterans, and/or military beneficiaries.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information. Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

- State the [FY21 TBIPHRP CRDA Focus Area\(s\)](#) to be addressed by the future clinical study.
- Describe the objectives and rationale for the development project ***in a manner that will be readily understood by readers without a background in science or medicine.***
- Describe the tasks that will be accomplished during the FY21 TBIPHRP CRDA period of performance and why they are critical to enabling the future clinical study.
- Describe the ultimate applicability of the future clinical study.
 - Describe the target population of the future clinical study.

- Describe the potential clinical applications, benefits, and risks.
- Describe the projected time it may take to achieve a patient-related outcome.
- Describe the likely contributions of the future clinical study to advancing TBI and/or psychological health research and/or patient care.
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the FY21 TBIPHRP CRDA mechanism, refer to the “*Suggested SOW Strategy Clinical Research*” document for guidance on preparing the SOW and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
- Indicate the number (and type, if applicable) of animals and/or human anatomical samples projected or required for each task and at each site.
- Allocate time within the period of performance to obtain local IACUC/IRB and DOD ORP approval. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- Identify cell line(s) and commercial or organizational source(s) to be used, if appropriate.
- **Attachment 6: Impact and Relevance to Military Health Statement (one-page limit): Upload as “Impact.pdf”.** This attachment should be written in a manner that will be *readily understood by readers without a background in science or medicine*.
 - Explain how the work described in the FY21 TBIPHRP CRDA project is necessary for the success of the future clinical study.
 - Describe how the near- and long-term impacts of the future clinical study are relevant to at least one sub-area within one of the two [FY21 TBIPHRP CRDA Focus Areas](#) and will lead to patient-related outcomes in TBI and/or psychological health.

- Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.
- Describe any potential issues that might limit the impact of the proposed research and provide approaches to mitigate.
- Describe how the proposed effort is responsive to the healthcare needs of Service Members, Veterans, and/or military beneficiaries.
- If an active-duty military, Veteran, or military family member population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population.
- If a non-military population will be used for the future clinical study, describe how the results will be relevant to active-duty military, Veteran, or military family member population(s).
- If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest and/or patient care for TBI and/or psychological health.
- **Attachment 7: CBPR Letter(s) of Commitment, if applicable (two-page limit per letter): Upload as “CBPR_letter.pdf”.** Provide a letter signed by each lived experience consultant or community-based partner(s) confirming their role and commitment to participate on the research team. The letter should include the qualifications and background of the lived experience consultant(s) or community-based partner(s) and their relevance to the intended target population and future clinical study.
- **Attachment 8: CBPR Statement, if applicable (three-page limit): Upload as “CBPR_PI.pdf”.** Describe the CBPR approach that will be used (e.g., LEC, partner organization, CAB, co-researcher model) and at what points CBPR will be employed in planning the future clinical study. The statement should also include:
 - 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 future clinical study.
 - Description of training that will be provided to both scientific researchers and community members on CBPR, decision making, and equitable participation.
 - Description of co-learning and capacity-building activities among all partners.
 - Description of resource allocation, decision making processes and authorship between scientific researcher and community partners (whether individuals or organizations).
- **Attachment 9: 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 10: 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.
- **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”.

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.

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 10](#). (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.

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

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that

determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

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

II.D.4. Submission Dates and Times

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

The maximum period of performance is **18** months.

The anticipated total costs budgeted for the entire period of performance will not exceed **\$300,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **\$300,000** total costs or using an indirect cost rate exceeding 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 **18** months.

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

- Travel in support of multidisciplinary collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meeting is to present project information or disseminate project results of the FY21 TBIPHRP CRDA.

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**, which are of equal importance:

- **Rationale for Future Clinical Study**
 - How well the research question to be addressed in the future clinical study and, if applicable, intervention to be tested is relevant to one or more of the [FY21 TBIPHRP CRDA Focus Areas](#).
 - If an intervention is to be tested in the future clinical study, how well the relevant information about its source, FDA approval/review status (as applicable), availability, efficacy, dosing (if applicable), and mechanism of action (if known) is described.
 - How well the scientific rationale, literature review, preliminary studies, and/or preclinical data lead to and support the development of the future clinical study.
 - How well the hypothesis or objectives of the future clinical study are described.
 - To what extent the anticipated outcomes of the future clinical study will provide/improve near-term benefits for individuals with TBI and/or psychological health conditions.
 - How well the anticipated target population for the future clinical study is described.
- **Impact and Relevance to Military Health**
 - To what extent the work described in the FY21 TBIPHRP CRDA project is necessary for the success of the future clinical study.
 - How the near- and long-term impacts of the future clinical study are relevant to at least one sub-area within one of the two [FY21 TBIPHRP CRDA Focus Areas](#) and will lead to patient-related outcomes in TBI and/or psychological health.
 - To what extent 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.
 - How well any potential issues that might limit the impact of the proposed research are described and approaches to mitigate those issues are appropriate.

- If an active-duty military, Veteran, or military family member population will be used in the proposed research project, how well the application describes the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population.
- If the anticipated study includes a non-military population for all or a portion of the future study, how well the application describes how the results will be applicable to active-duty military, Veteran, or military family member population(s).
- **Development Plan Strategy and Feasibility**
 - To what extent the work to be conducted during the FY21 TBIPHRP CRDA is justified as necessary for the initiation of the future clinical study.
 - To what extent potential problems and alternative approaches are identified.
 - To what extent the proposed timeline and plans to finalize the experimental design and develop the applicable clinical protocol and related documents (e.g., consent form, research data collection instruments) are feasible as described and achievable within the FY21 TBIPHRP CRDA period of performance.
 - How appropriate the plans are to develop applicable data collection/monitoring procedures, data analyses, and other data collection tools for the scope of the future clinical study.
 - To what extent the plans are feasible for obtaining all necessary regulatory approvals (e.g., IRB, IND/IDE application process), including timelines, milestones, and planned interactions with the FDA and plans for safety and clinical monitoring, including compliance with GCP, if applicable, and are likely to lead to success.
 - How feasible the timeline and plans are for coordination of IRB submission and approval at each study site, as applicable.
 - How well the statistical support requirements (including data analysis and clinical trial design modeling) and support needed for the future clinical study are addressed.
 - How appropriate the development plans for sample size calculation, statistical analyses, and human subject recruitment, if applicable, are for the proposed future clinical study.
 - How feasible the plans are for establishing access to the relevant study population.
 - How well the plan to share and disseminate data and other resources created by the future clinical study are described.
 - How well described the plans are for other required preparatory activities, and whether they are appropriate to enable the future clinical study.

For preclinical research to generate data specifically requested by the FDA:

- How well the proposed research is supported by communication(s) with the FDA.
 - How well the scientific rationale supports the proposed experiments.
 - How the aims, research design, hypotheses, and methods are relevant to the data requested by the FDA.
 - To what extent the statistical plan is appropriate for the proposed research.
 - How well the proposed experiments acknowledge potential problem areas and pitfalls and provides alternative approaches.
 - How thoroughly the Data and Research Resources Sharing Plan describes how data and resources generated will be shared with the research community.
- **Personnel**
 - To what extent the background, expertise, and levels of effort of the PI and key personnel are appropriate to support successful planning and development activities necessary to initiate a future clinical study.
 - How well plans are outlined that will develop and train the research team and obtain any research resource or professional collaborations/expertise for the future clinical study, as applicable.
 - As applicable, how well described the plans are for training team members.
 - If applicable, how the plans for the identification of recruitment of military-relevant subject matter expertise are described.
 - If applicable, 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.
 - If applicable, how well the CBPR approach that will be used (e.g., LEC, partner organization, CAB, co-researcher model) and at what points CBPR will be employed in planning the future clinical study are described.

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

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

- **Environment**

- If applicable, to what extent the intellectual and material property plan development described in [Attachment 2](#) is appropriate.
- If applicable, to what degree the commercialization strategy 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 FY21 TBIPHRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative impact and relevance to military health

II.E.2. 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.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the FY21 TBIPHRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that 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 200.88, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in 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 FY21 funds are anticipated to be made no later than September 30, 2022. 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 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, or other non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General 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 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](#); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General 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 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 if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP 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 CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week

(closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the 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 605a. The program announcement numeric version code will match the General Application Instructions version code 605.

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.
- 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 FY21 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 FY21 TBIPHRP Programmatic Panel members can be found at <https://cdmrp.army.mil/tbiphrp/panels/panels21>.*
- 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 FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). 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.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Clinical research or a clinical trial is proposed.
- Preclinical research is proposed without an accompanying communication from a regulatory agency in the Supporting Documentation ([Attachment 2](#)).
- The PI does not meet the eligibility criteria.
- Application fails to address at least one sub-area within one of the two [FY21 TBIPHRP CRDA Focus Areas](#).

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	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"	
	CBPR Letters of Commitment as Attachment 7 with file name "CBPR_letter.pdf" if applicable	
	CBPR Statement as Attachment 8 with the file name "CBPR_PI.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 9 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 10 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

Application Components	Action	Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget (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
AdjDs	Adjustment Disorders
ASRs	Acute Stress Reactions
B	Billion
CAB	Community Advisory Board
CBPR	Community-Based Participatory Research
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CRDA	Clinical Research Development Award
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
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
GCP	Good Clinical Practice
GUID	Global Unique Identifier
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
LEC	Lived Experience Consultation
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NINDS	National Institute of Neurological Diseases and Stroke

NPC	Non-Profit Corporation
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PH/TBIRP	Psychological Health and Traumatic Brain Injury Research Program
PI	Principal Investigator
PII	Personally Identifiable Information
PTSD	Posttraumatic Stress Disorder
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.

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

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

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

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

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

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

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

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

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

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

Military Health System Research Symposium
<https://mhsrs.amedd.army.mil/SitePages/Home.aspx>

Military Infectious Diseases Research Program
<https://midrp.amedd.army.mil>

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

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

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

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

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

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

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

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

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

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

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

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

U.S. Army Aeromedical Research Laboratory
<https://www.usaarl.army.mil/>

U.S. Army Combat Capabilities
Development Command
<https://www.army.mil/ccdc>

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

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

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

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

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

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

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

U.S. Department of Defense Blast Injury
Research Program
<https://blastinjuryresearch.amedd.army.mil/>

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

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

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

Walter Reed Army Institute of Research
<https://www.wrair.army.mil>

APPENDIX 3: SAMPLE FITBIR CONSENT LANGUAGE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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