

# **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**

### **Translational Research Award**

**Announcement Type: Initial**

**Funding Opportunity Number: HT942524 TBIPHRPTRA**

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

#### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Pre-(Proposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), June 27, 2024
- **Invitation to Submit an Application:** August 8, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, October 3, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, October 8, 2024
- **Peer Review:** December 2024
- **Programmatic Review:** February 2025

*This program announcement must be read in conjunction with the General Application Instructions, version 901. 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.”*

## TABLE OF CONTENTS

<b>I.</b>	<b>OVERVIEW OF THE FUNDING OPPORTUNITY.....</b>	<b>1</b>
<b>II.</b>	<b>DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY .....</b>	<b>3</b>
II.A.	Program Description.....	3
II.A.1.	FY24 TBIPHRP Translational Research Award (TRA) Focus Areas .....	3
II.A.2.	Award History .....	5
II.B.	Award Information .....	5
II.C.	Eligibility Information.....	13
II.C.1.	Eligible Applicants .....	13
II.C.2.	Cost Sharing.....	14
II.C.3.	Other .....	14
II.D.	Application and Submission Information.....	14
II.D.1.	Location of Application Package .....	14
II.D.2.	Content and Form of the Application Submission .....	15
II.D.2.a.	Step 1: Pre-Application Submission .....	16
II.D.2.b.	Step 2: Full Application Submission .....	19
II.D.2.c.	Applicant Verification of Full Application Submission in eBRAP .....	39
II.D.3.	Unique Entity Identifier (UEI) and System for Award Management (SAM) .....	39
II.D.4.	Submission Dates and Times.....	39
II.D.5.	Funding Restrictions.....	39
II.D.6.	Other Submission Requirements .....	42
II.E.	Application Review Information .....	42
II.E.1.	Criteria .....	42
II.E.2.	Application Review and Selection Process.....	47
II.E.3.	Integrity and Performance Information.....	48
II.F.	Federal Award Administration Information .....	48
II.F.1.	Federal Award Notices.....	48
II.F.2.	PI Changes and Award Transfers.....	49
II.F.3.	Administrative and National Policy Requirements.....	49
II.F.4.	Reporting.....	50
II.G.	Federal Awarding Agency Contacts.....	51
II.G.1.	eBRAP Help Desk.....	51
II.G.2.	Grants.gov Contact Center .....	51
II.H.	Other Information.....	51
II.H.1.	Program Announcement and General Application Instructions Versions.....	51
II.H.2.	Administrative Actions.....	51
II.H.3.	Full Application Submission Checklist .....	55
<b>APPENDIX 1:</b>	<b>ACRONYM LIST .....</b>	<b>57</b>
<b>APPENDIX 2:</b>	<b>DOD AND VA WEBSITES.....</b>	<b>59</b>
<b>APPENDIX 3:</b>	<b>ADDITIONAL FOCUS AREA INFORMATION.....</b>	<b>61</b>

## II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

### II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. In FY07, Congress appropriated funding for traumatic brain injury (TBI) and psychological health research in response to the TBIs sustained and psychological health issues experienced by our deployed forces in Iraq and Afghanistan. The TBIPHRP complements ongoing Department of Defense (DOD) efforts toward promoting a better standard of care for TBI and psychological health in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. Appropriations for the TBIPHRP from FY07 through FY23 totaled \$2.4 billion. The FY24 appropriation is \$175.0 million (M).

The TBIPHRP's vision is to optimize the prevention, assessment, and treatment of psychological health conditions and/or traumatic brain injuries (TBIs). The program seeks to fund research that understands, prevents, and treats psychological health conditions and/or traumatic brain injuries that accelerates solutions to improve the health and health care of Service Members, their Families, Veterans, and the American public. ***Proposed research can be aligned with TBI, psychological health, or in combination.***

#### II.A.1. FY24 TBIPHRP Translational Research Award (TRA) Focus Areas

To meet the intent of the funding opportunity, applications ***must address at least one sub-area (e.g., 1a, 1b, 2a, 2b, etc.)*** within one of the three FY24 TBIPHRP TRA Focus Areas listed below. Bulleted items are provided in [Appendix 3](#) to indicate additional context regarding programmatic intent but are not required to be specifically addressed by applications. ***Proposed research must be hypothesis driven and can be aligned with TBI, psychological health, or in combination.*** Applications consisting solely or primarily of planning, engineering, manufacturing, or formulation activities may be administratively withdrawn. Selection of the appropriate FY24 TBIPHRP TRA Focus Area is the responsibility of the applicant.

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

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

- a. Understanding of risk, protective, and biological factors contributing to an individual's vulnerability to, response to, and long-term outcomes of psychological health conditions and/or TBI.
  - b. Understanding psychological health factors or outcomes associated with sexual harassment and assault perpetration, victimization, barriers to reporting and response. Studies that ensure participant anonymity are strongly encouraged.
2. **Prevent and Assess:** Research will address the prevention, screening, diagnosis, or prognosis of psychological health conditions and/or TBI.
- a. Identification and validation of biomarkers or other objective methods for assessment, diagnosis, prognosis, or real-time monitoring of psychological health conditions and/or TBI (including subclinical presentations) and associated sequelae of these conditions.
    - Development of decision-making frameworks or tools that incorporate objective assessments and may consider long-term outcomes to inform return to activity/duty decisions are within scope.
  - b. Development and evaluation of approaches or tools to prevent or reduce risk of psychological health conditions and/or TBI.
  - c. Development and evaluation of crosscutting prevention approaches<sup>1</sup> to address multiple adverse outcomes such as suicide, interpersonal violence (including intimate partner and family violence), and psychological health issues are within scope.
  - d. Development and evaluation of solutions to support military and family readiness<sup>2</sup> and increase psychological resilience in individuals to the potential negative impacts of specific military and life stressors.
3. **Treat:** Research will address novel and repurposed interventions<sup>3</sup> to improve outcomes of psychological health conditions and/or TBI. Efforts that address treatment, rehabilitation, and health services research are within scope.
- a. Interventions that promote sustained functional recovery, including interventions administered acutely, during the post-acute phase, or during the chronic phase of injury.

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<sup>1</sup> Crosscutting prevention approaches refer to strategies that enhance protective factors and reduce risk factors at multiple socio-ecological levels (e.g., individual, relationship, and community). [https://www.sapr.mil/sites/default/files/PPoA\\_2.0.pdf](https://www.sapr.mil/sites/default/files/PPoA_2.0.pdf)

<sup>2</sup> Military readiness is the ability of military forces to fight and meet the demands of assigned missions. Family readiness is the state of being prepared to effectively navigate the challenges of daily living experienced in the unique context of military service. <https://www.tradoc.army.mil/wp-content/uploads/2020/10/AD1029823-DOD-Dictionary-of-Military-and-Associated-Terms-2017.pdf>

<sup>3</sup> Intervention repurposing is the identification of novel indication(s) for a U.S. Food and Drug Administration-approved intervention.

- b. Development of postvention<sup>4</sup> strategies to support individuals in workplace or community environments following a sexual assault, suicide event, or other trauma.
- c. Health services research to improve provider adoption of evidence-based practices, improve access, and reduce barriers. In addition, factors that influence treatment engagement, follow-up care, and improvement of long-term outcomes are of interest.

## II.A.2. Award History

The TBIPHRP TRA Award mechanism was first offered in FY21. Since then, 234 TRA applications have been received, and 38 have been recommended for funding.

## II.B. Award Information

The FY24 TBIPHRP TRA intends to accelerate the conversion of research findings in psychological health and/or TBI into clinical applications. ***Funded research outcomes should lead to the development of health care products, technologies, and/or clinical practice guidelines that improve patient outcomes.*** Additional information about translational research can be found here: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2829707/> and <https://ncats.nih.gov/about/about-translational-science>.

***Applications may include preclinical applied research (including animal research) and clinical research (including pilot/exploratory clinical trials).*** The FY24 TBIPHRP TRA may also support ancillary studies that are associated with an ongoing or completed clinical trial and projects that optimize the design of future clinical trials. This award may not be used to support studies requiring an exception from informed consent ([EFIC](#)). Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs or biologics), diagnostics, devices, therapies, clinical guidance, behavioral interventions, emerging approaches and technologies, and/or new indications for products currently U.S. Food and Drug Administration (FDA)-approved or -cleared.

***Basic research is not allowed:*** Basic research is defined as research directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward process or products in mind.

***Preliminary data are required:*** Applications must include preliminary and/or published data to support the proposed research project.

***The FY24 TBIPHRP TRA allows funding for a pilot/exploratory clinical trial as PART of the funded research project*** where limited clinical testing of a novel knowledge product,<sup>5</sup> intervention, or device is necessary to inform the next step in clinical translation. Such

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<sup>4</sup> “Postvention” is defined the response to and care for individuals affected in the aftermath of a sexual assault, suicide event, or other trauma” (adapted from U.S. Department of Health and Human Services Office of the Surgeon General and National Action Alliance for Suicide Prevention, 2010, p. 141).

<sup>5</sup> A “knowledge product” is a non-tangible product that addresses an identified need, topic area, or capability gap; aims to transition into medical practice, training, or tools or to support materiel solutions; and educates or impacts behavior throughout the continuum of care, including prevention of negative outcomes.

pilot/exploratory clinical trial studies should be small, make up only a portion of the research proposed in the Statement of Work (SOW), and be utilized to establish the feasibility of a potential approach or to aid in device or intervention refinement. Applications that include large-scale clinical trials do not meet the intent of the mechanism. ***Applications that consist entirely of a pilot/exploratory clinical trial or multiple pilot/exploratory clinical trials may be administratively withdrawn.***

***A clinical trial is defined*** in 45 CFR 46.102 as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials. For more information, a Human Subject Resource Document is provided at <https://cdmrp.health.mil/pubs/pdf/Human%20Subjects%20Resource%20Document.pdf>.

***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research*** encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

- (1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
- (2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.
- (3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under [§46.104\(d\)\(4\) of the Common Rule](#).

***Applications that include a clinical trial as part of the proposed research will have additional submission requirements and review criteria.*** For more information, see [Section II.D.2, Content and Form of the Application Submission](#) and [Section II.E.1, Criteria](#). Funded clinical trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219.

**Multi-Institutional Clinical Research/Trials:** As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research ***must*** rely on a single Institutional Review Board

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

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

**Research Levels:** The FY24 TBIPHRP TRA offers funding for two Research Levels (refer to Section II.D.5 Funding Restrictions). Only one Research Level category may be chosen per application. It is the responsibility of the applicant to select the level that aligns with the scope of the proposed research. The Research Level should be selected based on the research scope and not on the amount of the budget. The following are generalized descriptions of the scope of the research appropriate for each Research level:

- **Research Level 1:** Research Level 1 is intended to support smaller scope, less complex preclinical and/or clinical research. **Pilot clinical trials as part of the proposed research** are allowed. The maximum period of performance is 3 years. The application's direct costs budgeted for the entire period of performance should not exceed \$500,000.
- **Research Level 2:** Research Level 2 is intended to support larger scope, more complex preclinical and/or clinical research. **Pilot clinical trials as part of the proposed research** are allowed. The maximum period of performance is 4 years. The application's direct costs budgeted for the entire period of performance should not exceed \$1.0M.
  - **Early-Career Investigator Partnering Option:** The FY24 TBIPHRP TRA (Research Level 2 only) includes an Early-Career Investigator Partnering Option that is structured to accommodate two Principal Investigators (PIs), one of whom is an Early-Career Investigator. The **combined direct costs** budgeted for the entire period of performance in the applications of the **Initiating PI and Partnering PI should not exceed \$1.0M**.
  - The PIs may have experience in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application. One PI will be identified as the Initiating PI and will be responsible for most of the administrative tasks associated with application submission. The other investigator will be the Partnering PI. At least one of the Initiating or Partnering PIs must be an Early-Career Investigator.
  - The intent is not to create a mentor-mentee arrangement. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. The application is expected to describe how the PIs' unique experience/expertise combined as a partnership will better address the research question, how the unique experience/expertise that each

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

- If recommended for funding, each PI will be named to an individual award within the recipient organization(s). For individual FY24 TBIPHRP TRA submission requirements for the Initiating and Partnering PI, refer to [Section II.D.2, Content and Form of the Application Submission](#).

**Rigor of Preclinical Research Design:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 ([www.nature.com/nature/journal/v490/n7419/full/nature11556.html](http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html)). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit [Attachment 9](#), Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>.

***If animal models are proposed, consider the following:***

- Pairing clinical populations to animal models in order to validate the clinical relevance and development of prevention, assessment, and treatment solutions is encouraged.
- Proposed animal models should be well justified, supported within the literature, and clearly align with clinical relevance to the human condition.

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

- Explanation of how the project addresses an aspect of psychological health conditions and/or TBI that has direct relevance to the health and/or readiness of Service Members, their Families, and Veterans.
- Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need.
- Use of military or Veteran populations, samples, or datasets in the proposed research, if appropriate.

Collaborations between researchers or consultants at military or Veterans organizations and non-military organizations are strongly encouraged. These relationships can leverage knowledge,



infrastructure, and access to unique data and research resources that the partners bring to the research effort, ultimately advancing TBI and psychological health research of significance to Service Members, their Families, and Veterans. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in [Appendix 2](#).

**Conducting DOD-Funded Human Research with Military Populations:** There are unique requirements and prohibitions for compensating DOD-affiliated personnel for study participation and for conducting research with military families/children and U.S. Army Special Operations Command populations. Additional information regarding conducting DOD-funded human research with military populations can be found at [https://cdmrp.health.mil/pubs/pdf/Conducting%20Research%20Military%20Pop%20DoD\\_funded\\_7NOV2022.pdf](https://cdmrp.health.mil/pubs/pdf/Conducting%20Research%20Military%20Pop%20DoD_funded_7NOV2022.pdf).

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

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

**Nuclear Medicine:** Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

**Women's Health:** The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

**Optimizing Research Impact Through Community Collaboration:** Research funded by the FY24 TBIPHRP should be responsive to the psychological health conditions and/or TBI needs of the lived experience/consumer, family, and care provider communities. Through establishment and utilization of effective and equitable collaborations and partnerships, the translational and impact potential of the proposed research can be maximized. *For the FY24 TBIPHRP TRA, inclusion of Community-Based Participatory Research (CBPR) approaches is encouraged,*

*particularly for studies involving human subjects, but not required.* The inclusion of CBPR can be documented in [Attachment 13](#), CBPR Documentation.

CBPR supports collaborative research that involves scientific researchers and community members working together to address diseases and conditions, particularly those that disproportionately affect health disparity populations. Recognizing the strength of each partner, scientific researchers and community members ***collaborate and contribute equitably their expertise on all aspects of the project, which may include a needs assessment, planning, research intervention design, implementation, evaluation, and dissemination.*** CBPR features shared responsibility for and ownership of the research project, and the research results are jointly interpreted, disseminated, and fed back to affected communities and may be translated into interventions or policy. CBPR methods are critically important for community-level interventions and conditions affecting health disparity populations. CBPR methods, such as collaborative planning, data collection, analysis/interpretation, dissemination and implementation, actively engage consumers and communities in research. These interactions can accelerate “bench to bedside” translation and augment the potential impact of research on people living with psychological health conditions and/or TBI.

CBPR collaborative relationships are often established through integrating community members into research teams as co-researchers, advisors, and consultants. Some examples of CBPR collaborations include:

- **Lived Experience Consultants/Consumers:** The research team includes at least one member with lived psychological health conditions and/or TBI experience who will provide advice and consultation throughout the planning and implementation of the research project. Lived Experience Consultants (LECs) may include individuals with a TBI or psychological health condition, their family members, or care partners. Ideally an LEC should be an individual(s) nominated by a foundation or advocacy group in order to represent the diversity of those with TBI or psychological health conditions vs. individual experiences.
- **Partnership with a community-based organization:** The research team establishes partnerships with at least one community-based organization that provides advice and consultation throughout planning and implementation of the research project. Community-based organizations may include advocacy groups, service providers, policymakers, or other formal organizational stakeholders.
- **Community Advisory Board (CAB):** A CAB is composed of multiple community stakeholders and can take many forms, from a board of LECs to a coalition of community-based organizations or any combination thereof. As with LECs and organizational partners, the CAB provides advice and consultation throughout planning and implementation of the research project.

Additional information on CBPR can be found here:

- Chung B, Jones L, Dixon EL, et al. 2010. [Using a community partnered participatory research approach to implement a randomized controlled trial: Planning the design of](#)

[community partners in care](#). *Journal of Health Care for the Poor and Underserved* 21(3):780-795. doi: 10.1353/hpu.0.0345.

- Wallerstein N and Duran B. 2010. [Community-based participatory research contributions to intervention research: The intersection of science and practice to improve health equity](#). *American Journal of Public Health* 100(S1):S40-S46. doi: 10.2105/AJPH.2009.184036.
- Patient-Centered Outcomes Research Institute's Engagement Tool and Resource Repository, <https://www.pcori.org/engagement/engagement-resources/Engagement-Tool-Resource-Repository>.
- Toolkit to Better Understand and Measure Stakeholder Engagement, <https://icdr.acl.gov/resources/reports/getting-most-out-stakeholder-engagement-toolkit-better-understand-and-measure>.

**Data Sharing Requirement for Traumatic Brain Injury or Psychological Health Human Subjects Research:** The CDMRP intends that information, data, and research resources generated under this funding opportunity will be made available to the research community (including both the scientific and consumer advocacy communities) and the public at large. Note that the CDMRP will not serve as the government sponsor or signatory on any data-sharing agreements. For additional guidance, refer to the General Application Instructions, Appendix 2, Section L.

- **All Prospective Human Subject Research**

- Applicants **must** include language in informed consent documents to allow for submission of de-identified data to a repository or for secondary use/meta-analyses of the data.
- Applicants are also strongly encouraged to include language in consent forms to enable optional passive follow-up via electronic health record.
- ***The TBIPHRP requires applicants to incorporate Common Data Elements (CDEs) appropriate to each field of study*** such as the [PhenX Core and Specialty collections](#) and National Institute of Neurological Disorders and Stroke (NINDS) [TBI CDEs](#). ***Justification is required*** if CDEs are not utilized.
- As applicable, applicants are strongly encouraged to include secondary outcomes in proposed studies to address potential crosscutting impacts.
- As appropriate, the inclusion of TBI, psychological health, and caregiver/family outcomes measures is encouraged, regardless of the primary focus of the study.

- **Psychological Health Research**

- The TBIPHRP requires that all psychological health-related clinical research data with at least 50 subjects funded by this program be shared through the National Institute of Mental Health (NIMH) Data Archive (NDA). The NDA provides an infrastructure for

sharing research data, tools, methods, and analyses enabling collaborative science and discovery. The NDA mission is to accelerate scientific research and discovery through data sharing, data harmonization, and the reporting of research results. Consult the NDA website at <https://nda.nih.gov/> for additional information.

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

- **Traumatic Brain Injury Research**

- The TBIPHRP requires that all TBI-related clinical research data with at least 50 subjects funded by this program be shared through the jointly supported DOD-National Institutes of Health (NIH) Federal Interagency TBI Research Information System (FITBIR). Recipients will be required to upload study data annually and in accordance with the FITBIR data submission policies. There is no fee to use FITBIR, and detailed guidance and policies, including a cost estimator tool for budgeting considerations, can be found at <https://fitbir.nih.gov>.
- While there is no direct charge to users of the FITBIR Informatics System, a project [estimation tool](#) is available to help estimate costs and manpower needs that may be associated with data submission.

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

- Applicants proposing to conduct research collecting both TBI and psychological health human subject data may follow the requirements for either TBI research, psychological health research, or both as appropriate. Applicants should justify their choice.

The types of awards made under the program announcement will be assistance agreements. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the CDMRP during the project's period of performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of the CDMRP is anticipated, a grant will be made (31 USC 6304). Conversely, if "substantial involvement" on the part of the CDMRP is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement means that, after the award, CDMRP staff will assist, guide, coordinate, or participate in project activities including but not limited to:

- Making recommendations for continued funding based on (a) overall study progress, including sufficient patient and/or data accrual, and/or (b) maintenance of a high quality of research

The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY24 TBIPHRP TRA should not exceed **\$500,000 (Research Level 1)** or **\$1.0M (Research Level 2)**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

*The CDMRP expects to allot approximately \$17.05M to fund approximately six TRA Research Level 1 applications and eight TRA Research Level 2 applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer 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 FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.*

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

**II.C.1.a. Organization:** Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

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

**Intramural DOD Organization:** Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible *organizations*, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

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

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

#### **II.C.1.b.i. Single PI Option**

Principal Investigator: Independent investigators at all academic/career levels (or equivalent) may be named by organizations as the PI on the application. For titles outside of academia that may not be analogous to traditional hierarchies, investigators at or above an independent scientist level may be named by their organization as the PI on the application. *Postdoctoral fellows are not considered independent investigators.*

### **II.C.1.b.ii. Research Level 2 Early-Career Investigator Partnering Option**

For applications that select the Early-Career Investigator Partnering Option, both PIs must be independent investigators, and the early-career investigator must be within 10 years after completion of their terminal degree by the time of the application submission deadline (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is included. Lapses in research time or appointments as denoted in the biographical sketch should be explained in the application. For Early-Career Investigator Partnering Option applications, at least one of the named PIs *must* be an Early-Career Investigator.

*Postdoctoral fellows are not considered independent investigators.*

### **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 to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

## **II.D. Application and Submission Information**

### **II.D.1. Location of Application Package**

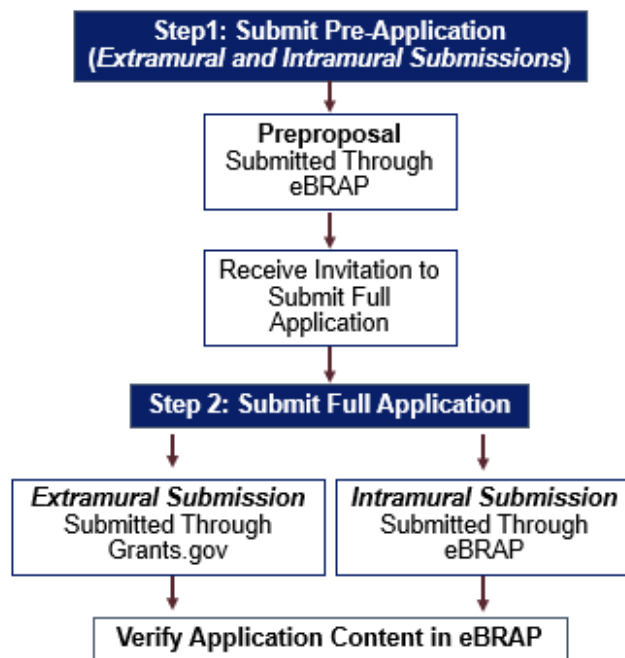
Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

**eBRAP** (<https://ebrap.org>) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

**Grants.gov** (<https://grants.gov>) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

### *Application Submission Workflow*



**Extramural Submission:** An application submitted by an [extramural organization](#) for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524TBIPHRPTRA from Grants.gov (<https://grants.gov>). Full applications from extramural organizations **must** be submitted through Grants.gov.

**Intramural Submission:** An application submitted by an [intramural DOD organization](#) for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524 TBIPHRPTRA from the anticipated submission portal eBRAP (<https://ebrap.org>) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

***Submitting applications that 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).***



Unnecessary duplication of funding or accepting funding from more than one source for the same research, is prohibited. See the CDMRP's full position on research duplication at <https://cdmrp.health.mil/funding/researchDup>.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 TBIPHRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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

All pre-application components must be submitted by the PI or Initiating PI through eBRAP (<https://eBRAP.org/>), including the submission of contact information for the Partnering PI if exercising the Research Level 2 Early-Career Investigator Partnering Option.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for each PI, the Business Official(s), performing organization(s), and contracting organization(s) must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 prior to the application submission deadline.

**Research Level 2 Early-Career Investigator Partnering Option:** After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. *The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.* If not previously registered, the Partnering PI must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI should email the eBRAP Help Desk ([help@ebrap.org](mailto:help@ebrap.org)) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

***Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI.*** Partnering PIs are urged to complete these steps as soon as possible. If they are not completed:

- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.



- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

When starting the pre-application, applicants will be asked to select a “Mechanism Option”. Please be sure to select the correct option appropriate to your pre-application:

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

#### II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for additional information on pre-application submission):

**Note:** *Upload documents as individual PDF files unless otherwise noted.*

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

The Preproposal Narrative should include the following:

- Focus Area:** Describe how the proposed project is relevant to the selected sub-area(s) within one of the three [FY24 TBIPHRP TRA Focus Areas](#).
- Rationale:** State the ideas and reasoning on which the proposed work is based; include relevant preliminary data and literature citations. Concisely state the project’s objectives and specific aims. Identify and justify the requested [Research Level](#). If applicable, identify the availability of and accessibility to the intervention. As applicable, provide the regulatory status (including device classification) and identify the regulatory sponsor.
- Research Team:** Briefly state the qualifications and expected contributions of the PI(s) and key personnel to successfully complete the described research project. Note any DOD or VA collaborations.
- Impact and Relevance to Military Health:** Describe the potential near-term and long-term impact of the proposed research on a critical problem or question in psychological health and/or TBI research or patient care. Explain how the project is relevant to the health care needs of Service Members, their Families, and/or Veterans.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:
  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
  - **Key Personnel Biographical Sketches (six-page limit per individual):** *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

#### II.D.2.a.ii. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the TBIPHRP, pre-applications will be screened based on the following criteria:

- **Focus Area:** The degree to which the proposed research is relevant to the selected sub-area(s) within one of the three [FY24 TBIPHRP TRA Focus Areas](#).
- **Rationale:** How well the ideas and reasoning on which the proposed work is based is supported by relevant preliminary data and literature citations and is appropriate for the [Research Level](#) requested. If applicable, to what extent the availability of and accessibility to the research resources and subject population will support successful completion of the research.
- **Research Team:** How the qualifications and expected contributions of the PI(s) and other key personnel are appropriate to successfully complete the described research project.
- **Impact and Relevance to Military Health:** The degree to which the proposed research will have an impact a critical problem or question in psychological health and/or TBI research or patient care. How well the research is relevant to the health care needs of Service Members, their Families, and/or Veterans.

#### II.D.2.a.iii. Notification of Pre-Application Screening Results

Following the pre-application screening, Initiating PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in [Section I, Overview of the Funding Opportunity](#). No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based

on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

#### **II.D.2.b. Step 2: Full Application Submission**

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

##### **II.D.2.b.i. Full Application Submission Type**

**Extramural Submissions:** Full applications from extramural organizations *must* be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

**Intramural Submissions:** Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

##### **II.D.2.b.ii. Full Application Submission Components for the PI or Initiating PI**

**Research Level 2 Early-Career Investigator Partnering Option:** The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. *All associated applications (the Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.*

Each application submission must include the completed full application package for this program announcement. See [Section II.H.3](#) of this program announcement for a checklist of the required application components.

**(a) SF424 Research & Related Application for Federal Assistance Form (Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B, for detailed information.

##### **(b) 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 2.

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

Describe the proposed project in detail using the outline below.

- **Background:** State the relevance of the proposed research and applicability of the anticipated findings to adhere to the intent of the mechanism and the selected *sub-area(s) within one of the three* [FY24 TBIPHRP TRA Focus Areas](#). Describe in detail the scientific rationale for the study and include a literature review, unpublished data, preliminary studies/data, and/or preclinical data that support the development of the proposed project. The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or hypotheses. Provide a summary of relevant prior preclinical and/or clinical work and distinguish how the proposed study differs from other relevant or recently completed research. If applicable, describe any CBPR/stakeholder engagement that was performed and how it helped to formulate the hypothesis/objective and research strategy. If applicable, full details of the CBPR approach can be provided in [Attachment 13](#).
- **Objectives/Specific Aims/Hypothesis:** Describe how the proposed research aligns with the intent of the mechanism. Provide a description of the purpose and objectives of the study with detailed specific aims and hypotheses. Specific aims should be independent and not depend on the successful completion of prior aims. The aims should align with the associated tasks described in the SOW ([Attachment 5](#)). If the proposed research project is part of a larger study, present only those tasks that this FY24 TBIPHRP TRA would fund.
- **Research Strategy and Feasibility:**
  - Identify and describe how the study design, methods, models, and analyses will meet the project’s goals and milestones.
  - Describe how the proposed project is feasible and will be completed within the proposed performance period.
  - Address potential problem areas and pitfalls and provide alternative methods and approaches.
  - If animals are to be used, justify why the proposed animal model(s) were chosen and discuss the model’s clinical relevance to the human condition. Additional detailed information regarding animal model relevance and experimental procedures will be required in the Animal Research Plan ([Attachment 9](#)).

- For studies performing retrospective or prospective human subject recruitment or observation, describe the population(s) of interest and how access to the population(s) or dataset(s) will be achieved; ***full details on human subject recruitment will be required in the Clinical Strategy Statement ([Attachment 10](#)) and/or Human Subject Recruitment and Safety Procedures ([Attachment 11](#)).***
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Include a complete power analysis (including method by which it was derived) to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application. If applicable, specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. 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.
- **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 government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support (three-page limit per letter is recommended):** 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 Commitment (if applicable, two-page limit per letter is recommended):** If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a Letter of Commitment from the commercial entity indicating availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.
- **Letters of Collaboration (if applicable) (two-page limit per letter is recommended):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.
- **Intellectual Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."
- **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data and Research Resources Sharing Plan:** Describe how data or resources generated during the performance of the project will be shared with the research community, including the sharing of de-identified data with repositories. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page <https://ebrap.org/eBRAP/public/Program.htm> for more information about CDMRP's expectations for making data and research resources publicly available. NIH-supported Data Repositories can be found at [https://www.nlm.nih.gov/NIHbmic/domain\\_specific\\_repositories.html](https://www.nlm.nih.gov/NIHbmic/domain_specific_repositories.html).
- **For applications involving FITBIR-eligible TBI research:**
  - ❖ Identify and describe the planned NINDS TBI CDEs, alignment to FITBIR data elements and forms, and timelines for integrating data to the FITBIR Informatics System. Provide a justification as to why existing CDEs are not applicable or appropriate.
  - ❖ Provide a justification as to why existing CDEs are not applicable or appropriate.



- ❖ For applications not using FITBIR, please justify and identify the alternative data-sharing platform.
- ***For applications involving NIMH NDA-eligible psychological health research:***
  - ❖ Identify and describe the planned CDEs appropriate to each field of study, data elements and forms, and timelines for integrating data to the NIMH NDA.
  - ❖ Provide a justification as to why existing CDEs are not applicable or appropriate.
  - ❖ For applications not using NIMH NDA, please justify and identify the alternative data-sharing platform.
- **Data Management Plan (if applicable, two-page limit is recommended):** If a Data Management Plan is included as part of the [Attachment 11](#), Human Subject Recruitment and Safety Procedures, then submission of the Data Management Plan under “Supporting Documentation” is not required. Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instruction 3200.12](#).
  - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.
  - For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Quad Chart:** Provide a Quad Chart for the proposed project. The format for the Quad Chart is available on the eBRAP “Funding Opportunities & Forms” web page at (<https://ebrap.org/eBRAP/public/Program.htm>).
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf”. The technical abstract is used by all reviewers. *Abstracts of all funded research projects will*

***be posted publicly.*** 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.

- **Background:** State how the proposed research addresses one or more sub-area within one of the three [FY24 TBIPHRP TRA Focus Areas](#). Present the ideas and reasoning behind the proposed work.
- **Objective/Hypothesis:** State the objective to be reached or the hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the experimental design, including model system(s)/research participant population(s) and appropriate controls. If proposing a clinical trial, identify the phase.
- **Impact:** Briefly describe the potential near-term and long-term impact of the results of the proposed research on psychological health conditions and/or TBI.
- **Relevance to Military Health:** Explain how the project is relevant to the health care needs of Service Members, their Families, and/or Veterans.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information. Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

- Describe the objectives and rationale for the proposed project.
- If applicable, describe the CBPR approach and implementation in the study.
- Describe the ultimate applicability of the research and how it addresses the selected ***sub-area(s) within one of the three*** [FY24 TBIPHRP TRA Focus Areas](#).



- Describe the types of patients that will be helped by the research and how it will help them.
  - Describe potential clinical applications, benefits, and risks.
  - Describe the projected timeline to achieve the expected patient-related outcome.
  - Describe how the proposed project will impact the health and well-being of Service Members, Veterans, and/or military beneficiaries.
- **Attachment 5: Statement of Work (five-page limit): Upload as “SOW.pdf”.** Refer to the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for the suggested SOW format and recommended strategies for assembling the SOW.

For the FY24 TBIPHRP TRA, refer to either the “Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work” or “Example: Assembling a Generic Statement of Work”, whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the “Suggested SOW Format” to develop the SOW for the proposed research. Submit as a PDF.

The SOW should state the specific aims described in the Project Narrative and include a list of major tasks and subtasks that support the completion of the stated aims, including milestones for completing the aims during the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also include the following tasks/subtasks:

- If applicable, cross-mapping of data elements to psychological health conditions and/or TBI CDEs.
- Including language in informed consent documents to allow for submission of de-identified data to a repository or for secondary use/meta-analysis of the data.
- FITBIR- or NIMH NDA-eligible research should also include the following subtasks:
  - Investigator and study registration within the first 30 days of the award
  - Sharing of draft data collection forms with FITBIR or NIMH NDA, as applicable
  - Annual data submissions

**Research Level 2 Early-Career Investigator Partnering Option:** Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.

- **Attachment 6: Impact Statement (two-page limit): Upload as “Impact.pdf”.** The Impact Statement must demonstrate alignment with the selected sub-area(s) within the

[FY24 TBIPHRP TRA Focus Areas](#) and should be written in a manner that will be *readily understood by readers without a background in science or medicine*.

- Describe how the proposed research will accelerate research in the selected sub-area(s) within the [FY24 TBIPHRP TRA Focus Areas](#) and will lead to the development of health care products, technologies, and/or clinical practice guidelines that improve patient outcomes.
  - Describe the anticipated short-term (immediate to 5 years) and long-term (greater than 5 years) impact of the proposed work on research or improved patient care.
- Describe any potential issues that might limit the impact of the proposed research and provide approaches to overcome.
- **Attachment 7: Relevance to Military Health Statement (two-page limit): Upload as “Military.pdf”.** Describe how the proposed effort is responsive to the health care needs of Service Members, their Families, and/or Veterans.
  - If applicable, clearly articulate how the proposed research is likely to enhance readiness and recovery on the battlefield, during training, or in resource-limited environments. *Note that, per [DOD Instruction 6200.02](#), the DOD preferentially uses medical countermeasures that are approved by the United States Food and Drug Administration.* Applicants should address this requirement if appropriate.
  - If applicable, describe how the study team composition can provide military-relevant subject matter expertise to the proposed research.
  - If applicable, describe how the proposed research project complements DOD and/or VA areas of research interest and/or patient care for psychological health conditions and/or TBI.
  - Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.
- **Attachment 8: Transition Plan (three-page limit): Upload as “Transition.pdf”.** Research funded by the TBIPHRP should accelerate the development of tangible or knowledge products that optimize the prevention, assessment, and treatment of psychological health conditions and/or traumatic brain injuries. In the Transition Plan, provide information on the methods and strategies proposed to move the research to the next phases of development or commercialization/clinical use following the successful completion of the proposed effort. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. The transition plan should include the components listed below, as appropriate.

*For the purposes of this funding opportunity Regulatory Agency refers to the U.S. Food and Drug Administration (FDA) or any relevant international regulatory agency unless otherwise noted.*

- Details of the overall strategy to transition to the next level of development or commercialization/clinical use. Include a description of collaborations and other resources that will be used to provide continuity of development.
- A brief schedule and milestones for transitioning to a clinical product (even if Regulatory Agency approval/clearance is not needed). This can include next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by a Regulatory Agency.
- For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.
  - A “knowledge product” is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, or tools or to support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities); and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
- If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government’s ability to access such products or technologies in the future.
- A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 9: Animal Research Plan (*Attachment 9 is required for applications utilizing animals; five-page limit per animal study*): Upload as “AnimRschPln.pdf”.** When the proposed study involves animals, the applicant is required to submit a plan describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the Institutional Animal Care and Use Committee (IACUC) as the Animal Research Plan. Applicants should consult the ARRIVE 2.0 guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and ultimately reported. The ARRIVE 2.0 guidelines can be found at <https://arriveguidelines.org/arrive-guidelines>. The Animal Research Plan should address the following points for each proposed animal study:
  - Briefly describe the research objective(s) of the animal study.
  - Provide evidence that the chosen animal model(s) is validated and well justified in the literature. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and the relevance to human biology.
    - Describe approaches that will be undertaken to validate or corroborate findings from animal studies to relevant human data sources/populations. This could

include, but is not limited to, validation of animal transcriptomic data using publicly available human transcriptomic datasets, confirmation of histological findings in a human postmortem case series, and validation against fluid-based or imaging biomarkers.

- Describe how the proposed validation approaches or corroborative studies “de-risk” the possibility that the findings from the animal study cannot be translated into human populations.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA (or international equivalent) or next stage of development, if applicable.
- **Attachment 10: Clinical Strategy Statement (no page limit): Upload as “Clinical.pdf”. (*Attachment 10 is required for applications that propose a pilot/exploratory clinical trial.*)** Applications that consist entirely of a pilot/exploratory clinical trial or multiple pilot/exploratory clinical trials may be administratively withdrawn.

For the FY24 TBIPHRP TRA, evidence of investigational product exemption (e.g., Investigational New Drug [IND] or Investigational Device Exemption [IDE]) application submission, clearance or authorization has been submitted/cleared/authorized or will be submitted to the appropriate Regulatory Agency ***within the first 60 days of the award*** must be included in the application. For the purposes of this funding opportunity Regulatory Agency refers to the FDA or any relevant international regulatory agency unless otherwise noted.

- **Rationale:**
  - Briefly describe the scientific rationale for the proposed pilot/exploratory clinical trial and the endpoints to be measured. Identify the clinical trial phase.
  - Provide a brief description of the product/intervention(s). Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs or biologics), diagnostics, devices, therapies, clinical guidance, behavioral interventions, emerging approaches and technologies, and/or new indications for

products currently U.S. Food and Drug Administration (FDA)-approved or -cleared.

- Describe how the pilot/exploratory clinical trial is clearly linked to the preclinical or clinical research studies that will also be performed through this award.
  - Describe how the proposed work is responsive to the intent of the FY24 TBIPHRP TRA in including only pilot/exploratory clinical testing of a novel intervention or device necessary to inform the next step in the continuum of translational research.
  - Describe how the pilot/exploratory clinical study is small, represents only a portion of the proposed SOW ([Attachment 5](#)), and will be utilized to establish feasibility of a potential approach or to aid in device or intervention refinement.
- ***For products/interventions that do not require regulation by a Regulatory Agency:***
- Provide evidence that the product/intervention(s) does not require regulation by a Regulatory Agency. Note that this request includes but is limited to software applications, algorithms, nutraceuticals, or behavioral health interventions. ***Submissions providing “not applicable,” “none,” or similar responses do not satisfy this request and may be administratively withdrawn.*** If the clinical trial will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements. No further information for this attachment is required.
- ***For products/interventions that require regulation by a Regulatory Agency:***
- For investigator-sponsored investigational product regulatory exemptions (e.g., IND, IDE) provide evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the Regulatory Agency.
  - State whether the product is FDA-approved, -licensed, or -cleared and marketed in the United States. State whether the product is approved, licensed, cleared and marketed outside of in the United States.
  - If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).
  - If the product is not currently Regulatory Agency-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA or international regulatory agency has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor

commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.

- ***For the FY24 TBIPHRP TRA, evidence that an investigational product regulatory exemption application (e.g., IND/IDE) has been submitted/cleared/authorized or will be submitted to the appropriate Regulatory Agency within the first 60 days of the award must be included in the application.*** The application should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. If an application has already been submitted to the Regulatory Agency, provide the date of submission, the application number, and a copy of the Regulatory Agency letter acknowledging the submission. Clearly identify whether a member of the study team holds the investigational product regulatory exemption (e.g., IND/IDE). If there are any existing cross-references in place, provide the investigational product regulatory exemption application (e.g., IND/IDE) number(s) and associated sponsor(s). Provide an explanation of the status of the investigational product regulatory exemption (e.g., IND/IDE) application (e.g., past the critical 30-day period, pending response to questions raised by the Regulatory Agency, on clinical hold, on partial clinical hold). Provide a summary of previous meetings with the Regulatory Agency on development of this product, if appropriate. A copy of the Regulatory Agency meeting minutes should be included if available. Provide copies of communications from the Regulatory Agency relevant to the most recent status of the investigational product regulatory exemption (e.g., IND/IDE).
- If available, provide a copy of the communication from the Regulatory Agency indicating the investigational product regulatory exemption (e.g., IND/IDE) application is active/safe to proceed.
- If an active investigational product regulatory exemption (e.g., IND/IDE) for the investigational product is in effect but an amendment is needed to include the proposed trial, describe the type and nature of the amendment(s) ***and provide evidence of the submission within the application.*** Indicate whether the amendment increases the risk of the intervention.
- If the proposed clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).
- **Attachment 11: Human Subject Recruitment and Safety Procedures (no page limit): Upload as “HumSubProc.pdf”. (*Attachment 11 is required for applications that propose recruitment of human subjects.*)**
  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts

at each study site. ***Demonstrate that the research team has access to the proposed study population at each site and describe the efforts that will be made to achieve accrual goals.*** Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. ***For clinical research/trial(s) proposing to include military personnel, refer to the General Application Instructions, Appendix 1, for more information.***

- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical research/trial. Describe how the inclusion and exclusion criteria meet the needs of the proposed clinical research/trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.
- **Inclusion Enrollment Plan:** Describe the strategy for the inclusion of women and minorities in the clinical research/trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.
- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them. Address the availability of human subjects for the clinical trial for each enrollment site. If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan. Describe the recruitment and advertisement materials. Discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress.
- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects (including vulnerable populations). ***This award may not be used to support studies requiring an EFIC.***



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



- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry.  
*Note:* Some screening procedures may require a separate consent or a two-stage consent process.
- **Risks/Benefits Assessment:**
  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
  - **Risk management and emergency response:**
    - ❖ Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (if applicable) will be managed and conducted. Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values. Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.
  - **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.
- **Data Management Plan:** Describe all methods used for data collection, including the following:
  - **Data:** The types of data, software, or other materials to be produced.
  - **Acquisition and processing:** How the data will be acquired, including the time and location of data acquisition, if scientifically pertinent. If use of existing data resources is proposed, describe the origin of the dataset. Provide an account of the standards to be used for data and metadata format and content. Explain how the data will be processed.
  - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
  - **Confidentiality:**
    - ❖ Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and

confidentiality of study records, particularly those containing identifying information, should be addressed.

- ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that DOD representatives are eligible to review study records.
- ❖ Address requirements for reporting sensitive information to state or local authorities.
- **Data capture, verification, and disposition:** Describe how data will be captured and verified, including the quality assurance and quality control measures taken during collection, analysis, and processing. Describe where data (both electronic and hard copy) will be stored; who will keep the data; how the data will be stored, if applicable; the file formats and the naming conventions that will be used; the process for locking the database at study completion; and the length of time that data will be stored, along with a justification for the time frame of preservation, which may include considerations related to the balance between the relative value of data preservation and other factors such as the associated cost and administrative burden of data storage. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For studies requiring Regulatory Agency oversight, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) is required.
- **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the Regulatory Agency, if applicable.
- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.
- **Laboratory Evaluations:** State the biospecimen that will be collected along with the collection schedule and amount. Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects). Describe the specimen storage plan, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the actions to be taken to allow the use of stored specimens in future research studies, if applicable. Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the

samples. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **Questionnaires and Other Research Data Collection Instruments, if applicable:** Include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.
- **Attachment 12: Partnership Statement (two-page limit): Upload as “Partnership.pdf”. (*Attachment 12 is only applicable and required for applications submitted under the Early-Career Investigator Partnering Option.*)**
  - Provide a statement confirming that the Early-Career Investigator meets the [eligibility requirements](#). *Postdoctoral fellows are not considered independent investigators.*
    - Provide the completion dates of the terminal degree and last postdoctoral/fellowship position.
    - Provide an explanation of any lapses in research time or appointments as denoted in the biographical sketch.
  - Describe how the partnership and combined experience/expertise of both PIs are critical to the research strategy and completion of the SOW.
  - Explain how the partnership will better address the research question and why the work should be done together rather than through separate individual efforts.
  - Explain how both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project.
  - Explain how funding will be balanced between both PIs, unless otherwise warranted and clearly justified.
- **Attachment 13: CBPR Documentation, if applicable (no-page limit): Start each document on a new page. Combine and upload as “CBPR.pdf”**
  - **CBPR Letters of Support (two-page limit per letter is recommended):** Provide a letter signed by each LEC/consumer or community-based partner(s) confirming their role and commitment to participate on the research team. The letter should include the qualifications and background of the LEC(s) or community-based partner(s) and their relevance to the proposed research project.
  - **CBPR Statement (three-page limit is recommended):** Description of the CBPR approach that will be used (e.g., LEC/consumer, partner organization, CAB, co-researcher model) and at what points it will contribute to the research project. Description of the CBPR input that will be captured and how this input will be

meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and dissemination of the research. Include a description of how CBPR effectiveness will be assessed. Description of training that will be provided to both scientific researchers and community members on CBPR approaches, decision-making, and equitable participation. Description of resource allocation, decision-making processes, and authorship between scientific researchers and community partners (whether individuals or organizations). Description of dissemination activities that will share research findings with the stakeholder communities.

- **Attachment 14: Representations (*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 8, Section B, Representations.
- **Attachment 15: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as “IGBudget.pdf”.** If an [intramural DOD organization](#) will be a collaborator in performance of the project, complete a separate budget using the “Suggested Intragovernmental/Intramural Budget Form”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The **total** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

**(c) Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

**(d) Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (six-page limit):** Upload as “Biosketch\_LastName.pdf”.
  - CBPR: If applicable, biographical sketches or equivalent documents should also be included for CBPR team member(s) to demonstrate background and experience relevant to their role in the proposed research project.
- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
- **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”.
- (e) Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.
- Early-Career Investigator Partnering Option:*** Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for the Partnering PI even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.
- (f) Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.
- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
  - **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as [Attachment 15](#).

#### **II.D.2.b.iii. Full Application Submission Components for the Partnering PI**

The application submission process for the Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

- (a) SF424 Research & Related Application for Federal Assistance Form (Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

**(b) Attachments:**

- **Attachment 5: Statement of Work (three-page limit):** Upload as “SOW.pdf”. Each PI must submit an identical copy of a jointly created SOW.

- **Attachment 14: Representations (*Extramural submissions only*):** Upload as “RequiredReps.pdf”.
  - **Attachment 15: Suggested Intragovernmental/Intramural Budget Form:** Upload as “IGBudget.pdf”.
- (c) Research & Related Personal Data:** For extramural submissions (via Grants.gov) refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section V.A.(c), for detailed information.
- (d) Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section V.A.(d), for detailed information.
- **PI Biographical Sketch (six-page limit):** Upload as “Biosketch\_LastName.pdf”.
  - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
  - **Key Personnel Biographical Sketches (six-page limit each):** Upload as “Biosketch\_LastName.pdf”.
  - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
- (e) Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.
- **Budget Justification (no page limit):** Upload as “BudgetJustification.pdf”.
- The Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*
- (f) Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, (via eBRAP), refer to General Application Instructions, Section V.A.(f), for detailed information.
- (g) Research & Related Subaward Budget Attachment(s) Form (*if applicable, Extramural Submissions Only*):** Refer to the General Application Instructions, Section IV.B.(g), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
- **Intramural DOD Subaward:** Complete the “Suggested Intragovernmental/Intramural Budget Form” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as [Attachment 15](#).

#### **II.D.2.c. Applicant Verification of Full Application Submission in eBRAP**

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the “Full Application Files” tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. 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 full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the [application verification period](#). The full application cannot be modified once the application verification period ends.

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

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/content/home>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

#### **II.D.4. Submission Dates and Times**

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.

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

#### **II.D.5. Funding Restrictions**

##### ***For Research Level 1:***

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

The application’s direct costs budgeted for the entire period of performance should not exceed **\$500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in

accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

***For Research Level 2:***

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

The application's direct costs budgeted for the entire period of performance should not exceed **\$1.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the 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 **4** years.

***For Research Level 2 Early-Career Investigator Partnering Option:***

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

The combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **\$1.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the direct costs of the primary award. A separate award will be made to each PI's organization.

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

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

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

- **Single PI:** In years three and four, travel costs for the PI to present project information or disseminate project results at a DOD-sponsored meeting (e.g., Interim/In-Progress Review



[IPR] meeting or Military Health System Research Symposium). For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area.

- **Early-Career Investigator Partnering Option:** In years three and four, travel costs for the Initiating and Partnering PIs to present project information or disseminate project results at a DOD-sponsored meeting (e.g., Interim/In-Progress Review [IPR] meeting or Military Health System Research Symposium). For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area.

May be requested for (not all-inclusive):

- Travel costs in support of multidisciplinary collaborations.
- Starting in year two, travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 TBIPHRP TRA.
- **Early-Career Investigator Partnering Option:** Starting in year 2, travel costs for the Initiating and Partnering PIs to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 TBIPHRP TRA.
- Costs associated with CBPR implementation.
- Research subject compensation and reimbursement for pilot clinical trial-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving, and resources/equipment to enable participation).
- Costs associated with data and research resource sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community):
  - Considerations
    - If recommended for funding, the government reserves the right to reduce the data/resource sharing budget request during negotiations in order to maximize funding available for research.
    - The TBIPHRP will not provide future TBIPHRP funds to preserve or share data/resources indefinitely.
  - Curation and developing supporting documentation, including formatting according to accepted community standards; de-identification; preparing metadata to foster discoverability, interpretation, and reuse; and formatting for transmission to and storage at a selected repository for long-term preservation and access.

- Local management considerations, such as unique and specialized information infrastructure necessary to provide local management and preservation (e.g., before deposit into an established repository).
- Preserving and sharing through established repositories, such as data deposit fees necessary for making data available and accessible. For example, if a Data Management and Sharing Plan proposes preserving and sharing scientific data for 3 years in an established repository with a deposition fee, the cost for the entire 3-year period must be paid prior to the end of the period of performance. If the Plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

## II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually evaluated according to the following **scored criteria**, of which, **Research Strategy and Feasibility** and **Clinical Strategy** (if applicable) are of most importance and the remaining criteria listed are of equal importance:

- **Research Strategy and Feasibility**
  - To what extent the relevance and applicability of the proposed research and anticipated findings adhere to the intent of the mechanism and selected sub-area(s) *within one of the three [FY24 TBIPHRP TRA Focus Areas](#)*.
  - How well the scientific rationale literature review, unpublished data, preliminary studies, and/or preclinical data support the development of the proposed project and provide the basis for the study questions and/or hypotheses.
  - How well the purpose and objectives of the study, with detailed specific aims and hypotheses, are described and align with the tasks in the SOW.
  - How well the study design, methods, models, and analyses are described and will meet the project's goals and milestones.
  - How well the application acknowledges potential problem areas and pitfalls and provides alternative approaches.
  - Whether the research is feasible and could be completed within the proposed period of performance.

- Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

***For studies performing animal research:***

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

• ***Clinical Strategy (for studies performing prospective human subject recruitment)***

- How well the application describes the scientific rationale for the proposed clinical research/trial and the endpoints to be measured.
- The degree to which the recruitment, screening, and retention processes for human subjects will meet the needs of the proposed study.
- Whether the application demonstrates access to the proposed study population at each site.
- How well the inclusion/exclusion criteria meet the needs of the proposed clinical research/trial.
- How well the application identifies any potential barriers to accrual/retention and provides mitigation plans for addressing unanticipated delays (e.g., slow accrual, attrition).
- How well plans to collect specimens and conduct laboratory evaluations are relevant to the study objectives, if applicable.
- To what degree the data collection instruments are appropriate to the proposed study.
- To what extent the distribution of the proposed enrollment on the basis of sex/gender, race, and/or ethnicity is appropriate for the proposed research.

***For applications including a pilot clinical trial***

- How well the proposed pilot clinical trial is responsive to the intent of the FY24 TBIPHRP TRA in including only pilot/exploratory clinical testing of a novel intervention or device necessary to inform the next step in the continuum of translational research.
- If applicable, whether evidence that the product/intervention does not require regulation by a Regulated Agency is provided and reasonable.
- As appropriate, whether the application includes evidence that the IND or IDE application (or international equivalent) has been submitted/cleared/authorized or will be submitted to the appropriate Regulatory Agency within the first 60 days of the award.
- If applicable, whether a member of the study team is the regulatory sponsor and whether the timeline proposed for the IND/IDE application for the proposed indication is appropriate.
- For investigator-sponsored investigational product regulatory exemptions (e.g., IND, IDE, or other international equivalent), whether there is evidence of appropriate institutional support and capabilities to ensure monitoring as required by the FDA.

- **Transition Plan**

- Whether the overall strategy described to transition the research to commercialization or clinical use is reasonable and achievable.
- Whether the schedule and milestones for transitioning the research to a clinical product are achievable.
- Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
- How well the application identifies intellectual property ownership and demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization.
- If applicable, how the application describes an appropriate intellectual and material property plan among participating organizations.
- If applicable, how well the application addresses any impact of intellectual property issues on product development and the government's ability to access such products or technologies in the future.

- **Impact**

- To what extent the proposed research will accelerate research in the selected sub-area(s) within the [FY24 TBIPHRP TRA Focus Areas](#) and will lead to the development of health

care products, technologies, and/or clinical practice guidelines that improve patient outcomes.

- How well the application acknowledges potential issues that might limit impact and provides approaches to overcome.

- **Personnel**

- To what degree the research team's background and experience/expertise are appropriate to accomplish the proposed work.
- Whether the levels of effort by the PI and other key personnel are appropriate to ensuring the success of the project.

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

- Whether the Early-Career Investigator meets the [eligibility requirements](#).
- To what degree the partnership and combined experience/expertise of both PIs are critical to the research strategy and completion of the SOW.
- To what degree the partnership will better address the research question together rather than through separate individual efforts.
- How well the application reflects that both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project.
- Whether funding will be balanced between both PIs or is otherwise warranted and clearly justified.

- **Ethical Considerations (*for applications recruiting human subjects*)**

- To what extent the level of risk to human subjects is minimized and how the safety monitoring and reporting is appropriate for the level of risk.
- To what degree privacy and confidentiality of study records are appropriately considered.
- To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.

- **Statistical Plan and Data Analysis**

- As applicable, describe how the randomization and blinding procedures for the study are appropriate, and specify any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results are described.
- If applicable, describe how the justification for not utilizing randomization and/or blinding is appropriate.

- How the statistical plan, including sample size and power analysis, is appropriate to meet the objectives of the study and all proposed correlative studies.
- If applicable, whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.

- **Data and Research Resources Sharing Plan**

- To what extent the data and resources generated during the performance of the project will be shared with the research community, including the sharing of de-identified data with data repositories.
- For studies with prospective human subject enrollment, how thoroughly the application incorporates CDEs appropriate to each field of study.
- For studies with prospective human subject enrollment, how well the application justifies any instances where existing CDEs are not applicable or appropriate (if applicable).

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

- **Community-Based Participatory Research (for applications that include [Attachment 13, CBPR Documentation](#))**

- To what extent CBPR/stakeholder engagement was performed and to what degree it helped formulate the project's hypothesis/objective and research strategy.
- To what extent the CBPR Letter(s) of Commitment describe the role and commitment of the lived experience or community-based partners on the research team.
- How well the CBPR approach that will be used (e.g., LEC, partner organization, CAB, co-researcher model) is described and at what points it will contribute to the overall program or research project.
- To what extent the CBPR input will be captured and meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and dissemination of the research.
- To what extent training that will be provided to both scientific researchers and community members on CBPR approaches, decision-making, and equitable participation.
- To what degree dissemination activities will share research findings with the stakeholder communities.

- **Budget**
  - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - To what degree the scientific environment and the accessibility of institutional/organizational resources support the proposed research.
  - Whether the quality and extent of institutional support are appropriate for the proposed project.
- **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 priorities of the DHP and FY24 TBIPHRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relative impact
  - 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.health.mil/about/2tierRevProcess>.

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 review panel. Violations of confidentiality can result in the dissolution 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 a third party is a crime in accordance with 18 USC 1905.

### **II.E.3. Integrity and Performance Information**

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

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. 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.F. Federal Award Administration Information**

### **II.F.1. Federal Award Notices**

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the TBIPHRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

***Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization.*** 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 (i.e., assistance agreement).***

***Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.***

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An 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. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

***If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

## **II.F.2. PI Changes and Award Transfers**

Unless otherwise restricted, changes in PI will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and, in most cases, will not be allowed. Approval of a transfer request will be on a case-by-case basis.

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 7, Section F, for general information on organization or PI changes.

## **II.F.3. 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 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

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

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the study in the NIH clinical trials registry, [www.clinicaltrials.gov](http://www.clinicaltrials.gov), prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

#### **II.F.4. Reporting**

Annual technical progress reports and quad charts as well as a final technical progress report and quad chart will be required. Annual and final technical reports must be prepared in accordance with the Research and Performance Progress Report (RPPR).

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

**PHS Inclusion Enrollment Reporting Requirement:** Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal

contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10.0M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

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

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

*Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission*

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

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

*Questions regarding Grants.gov registration and Workspace*

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

Email: [support@grants.gov](mailto:support@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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

### **II.H.2. Administrative Actions**

After receipt of pre-applications or full applications, the following administrative actions may occur.

#### **II.H.2.a. Rejection**

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

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

The following will result in administrative rejection of the full application:

- Submission of an application for which a letter of invitation was not issued.
- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- [Attachment 6](#), Impact Statement is missing.
- [Attachment 7](#), Relevance to Military Health Statement is missing.

***For Early-Career Investigator Partnering Option applications:***

- [Attachment 12](#), Partnership Statement is missing.

***For applications involving animal research:***

- [Attachment 9](#), Animal Research Plan, is missing.

***For applications proposing a pilot/exploratory clinical trial:***

- [Attachment 10](#), Clinical Strategy Statement, is missing.

***For applications recruiting human subjects:***

- [Attachment 11](#), Human Subject Recruitment and Safety Procedures, 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 full application:

- An FY24 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, including letters of support/recommendation. ***A list of the FY24 TBIPHRP Programmatic Panel members can be found at <https://cdmrp.health.mil/tbiphrp/panels/panels24>.***

- 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>).
- 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.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Application consists solely or primarily of planning, engineering, manufacturing, or formulation activities.
- The PI(s) does not meet the eligibility criteria.
- Proposed research consists entirely of pilot/exploratory clinical trial or multiple pilot/exploratory clinical trials.
- Basic research is proposed.
- A clinical research/trial is proposed that requires an EFIC.
- **Early-Career Investigator Partnering Option:** Failure to submit both (Initiating and Partnering PI) applications by the deadline.
- Application failed to address at least one sub-area within one of the three FY24 TBIPHRP TRA Focus Areas.

- Evidence is not provided that the investigational product regulatory exemption (e.g., IND/IDE) application has been submitted/authorized/cleared or will be submitted in the first 60 days of the award.
- Application does not demonstrate support for and access to relevant population(s) and/or resources(s).
- The invited application proposes a different research project than that described in the pre-application.

#### **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. Full Application Submission Checklist

Full Application Components	Uploaded	
	Single or Initiating PI	Partnering PI
<b>SF424 Research &amp; Related Application for Federal Assistance</b> <i>(Extramural submissions only)</i>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Summary (Tab 1) and Application Contacts (Tab 2)</b> <i>(Intramural submissions only)</i>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Attachments</b>		
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>	
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>	
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>	
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>	
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Impact Statement – Attachment 6, upload as “Impact.pdf”	<input type="checkbox"/>	
Relevance to Military Health Statement – Attachment 7, upload as “Military.pdf”	<input type="checkbox"/>	
Transition Plan – Attachment 8, upload as “Transition.pdf”	<input type="checkbox"/>	
Animal Research Plan <i>(if applicable)</i> – Attachment 9, upload as “AnimRschPln.pdf”	<input type="checkbox"/>	
Clinical Strategy Statement <i>(if applicable)</i> – Attachment 10, upload as “Clinical.pdf”	<input type="checkbox"/>	
Human Subject Recruitment Safety Procedures <i>(if applicable)</i> – Attachment 11, upload as “HumSubProc.pdf”	<input type="checkbox"/>	
Partnership Statement <i>(if applicable)</i> – Attachment 12, upload as “Partnership.pdf”	<input type="checkbox"/>	
CBPR Document <i>(if applicable)</i> – Attachment 13, upload as “CBPR.pdf”	<input type="checkbox"/>	
Representations <i>(Extramural submissions only)</i> – Attachment 14, upload as “RequiredReps.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Suggested Intragovernmental Budget Form <i>(if applicable)</i> – Attachment 15, upload as “IGBudget.pdf”	<input type="checkbox"/>	<input type="checkbox"/>

Full Application Components	Uploaded	
	Single or Initiating PI	Partnering PI
<b>Research &amp; Related Personal Data</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Senior/Key Person Profile (Expanded)</b>	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Budget</b> ( <i>Extramural submissions only</i> ) Include budget justification	<input type="checkbox"/>	<input type="checkbox"/>
<b>Budget</b> ( <i>Intramural submissions only</i> ) Include budget justification	<input type="checkbox"/>	<input type="checkbox"/>
<b>Project/Performance Site Location(s) Form</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Subaward Budget Attachment(s) Form</b> ( <i>if applicable</i> )	<input type="checkbox"/>	<input type="checkbox"/>

## APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting <i>In Vivo</i> Experiments
ASR	Acute Stress Reaction
CAB	Community Advisory Board
CBPR	Community-Based Participatory Research
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IPR	In-Progress Review
IRB	Institutional Review Board
LAR	Legally Authorized Representative
LEC	Lived Experience Consultant
M	Million
MIPR	Military Interdepartmental Purchase Request
NDA	NIMH Data Archive
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PTSD	Posttraumatic Stress Disorder
RPPR	Research Performance Progress Report

SAM	System for Award Management
SOW	Statement of Work
TBI	Traumatic Brain Injury
TBIPHRP	Traumatic Brain Injury and Psychological Health Research Program
TRA	Translational Research Award
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	U.S. Department of Veterans Affairs

## APPENDIX 2: DOD AND VA WEBSITES

Collaboration with DOD and/or VA investigators is 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.afrl.af.mil/AFOSR/>

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

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

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

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

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

Defense Health Agency  
<https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/>

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

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

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

Military Health System Research Symposium  
<https://mhsrs.health.mil/sitepages/home.aspx>

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### APPENDIX 3: ADDITIONAL FOCUS AREA INFORMATION

The information below in italics provides additional context regarding programmatic intent but **are not required** to be specifically addressed by applications.

*Psychedelic clinical trials involving eligible Service Members are allowed: Section 723 of the [National Defense Authorization Act](#) for Fiscal Year 2024 authorizes the DOD to conduct research involving psychedelic substances (e.g., 3,4-Methylenedioxy-methamphetamine, psilocybin, ibogaine, 5-Methoxy-N,N-dimethyltryptamine, and other plant-based alternative therapies) as treatments for TBI or posttraumatic stress disorder (PTSD). The Secretary of the DOD may authorize any member of the Armed Forces serving on active duty who is diagnosed with a covered condition (TBI or PTSD) to participate in a clinical trial. **Submissions including a clinical trial involving psychedelic interventions and Service Members are allowed and will openly compete with other research submissions during the application review and selection process.** Such trials recommended for funding may be subject to additional review and approval processes.*

1. **Understand:** Research will address knowledge gaps in epidemiology and etiology of psychological health conditions and/or TBI.
  - a. Understanding of risk, protective, and biological factors contributing to an individual's vulnerability to, response to, and long-term outcomes of psychological health conditions and/or TBI.
    - *Understanding psychological health trajectories associated with trauma (e.g., acute stress reactions, adjustment disorders, PTSD) and suicidality that incorporate internal and external factors. For example, factors could include time course, demographic characteristics, career progression, history of trauma exposure, and community and cultural factors.*
    - *Understanding how the approach to psychiatric diagnosis (e.g., acute stress reactions, adjustment disorders, PTSD) in the military relates to occupational impairment and/or military separation.*
    - *Understanding the role of genetics, endophenotypes, health demographics, previous injuries or repetitive exposures, psychological health conditions, pathophysiology, and environmental factors (e.g., extreme temperatures/pressures) on TBI.*
    - *Understanding the contribution of pre- and post-injury patient, family,<sup>6</sup> and caregiver education, as well as cultural, demographic, stigma, and bias factors that may relate to treatment-seeking and adherence.*
    - *Development and analysis of modeling from clinical data and other human data (e.g., electronic health records, exposure, training, and/or occupational data) to forecast*

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<sup>6</sup> "Family" should be broadly defined to include not just spouses, but also parents, significant others/fiancés/partners, children, caregivers, or close friends.



*the long-term and/or late effects of brain exposures, such as TBI, and co-occurring conditions.*

- *Development and analysis of communication and tools/technology adoption that would facilitate clinical translation and identification of risk factors, educational barriers, social determinates of health, and other factors that may impede clinical translation.*
- b. Understanding psychological health factors or outcomes associated with sexual harassment and assault perpetration, victimization, barriers to reporting and response. Studies that ensure participant anonymity are strongly encouraged.
- *Understanding processes of shame, stigma, and institutional betrayal among sexual assault victims and their units/teams and evaluation of approaches to mitigate these experiences. Experiences of marginalized groups, male victims, and victims of intimate partner and family violence are of particular interest.*
  - *Understanding how interpersonal and individual conditions, choices, behaviors, and psychological health are influenced by organizational-level factors relate to sexual assault and harassment prevention, perpetration, and response. Measurement and analysis of organizational-level factors, such as culture, climate, and training, beyond aggregating individual perceptions, are encouraged. Research could include the progression from sexual harassment to sexual assault and factors influencing sexual harassment.*
  - *Understanding barriers to reporting sexual assault and factors that contribute to retaliation within units/teams and evaluation of approaches to mitigate barriers, prevent retaliation, and improve psychological health outcomes of victims. Research could include data from influencers, bystanders, and perpetrators, as well as environmental, structural, and demographic factors (e.g., workplace culture, climate, senior leader diversity, age, gender).*
  - *Understanding the psychological health consequences of intimate partner and family violence.*
2. **Prevent and Assess:** Research will address the prevention, screening, diagnosis, or prognosis of psychological health conditions and/or TBI.
- a. Identification and validation of biomarkers or other objective methods for assessment, diagnosis, prognosis, or real-time monitoring of psychological health conditions and/or TBI (including subclinical presentations) and associated sequelae of these conditions.
- *Development of decision-making frameworks or tools that incorporate objective assessments and may consider long-term outcomes to inform return to activity/duty decisions are within scope.*

- b. Development and evaluation of approaches or tools to prevent or reduce risk of psychological health conditions and/or TBI.
- *Evaluation of environmental sensor data in aspects related to brain health and risk from brain blast and impact exposures.*
  - *Development of innovative materials and technologies that can prevent or reduce risk of TBI.*
  - *Generation of physiological evidence regarding the safety, efficacy, and utility of candidate neuroprotective measures. Animal models, if used, should be validated and well justified within the literature and should demonstrate clear alignment to clinical populations.*
  - *Validation of objective tools/methods for assessing and real-time health status monitoring of psychological health conditions and/or TBI.*
  - *Development of clinical decision-making frameworks or tools that incorporate objective assessments and long-term outcomes to return to activity/duty decisions.*
- c. Development and evaluation of crosscutting prevention approaches to address multiple adverse outcomes such as suicide, interpersonal violence (including intimate partner and family violence), and psychological health issues are within scope.
- *Optimized messaging for successful dissemination and implementation.*
  - *Inclusion of families<sup>7</sup> and evaluation of family impact.*
  - *Culturally acceptable approaches to reducing access to lethal means and promoting means safety for suicide and violence prevention.*
- d. Development and evaluation of solutions to support military and family readiness and increase psychological resilience in individuals to the potential negative impacts of specific military and life stressors.
- *Effective pharmacologic or non-pharmacologic prevention interventions. Solutions for prevention of acute stress reactions (ASRs) and PTSD or adjustment disorders may be proposed.*
  - *Preparation of Service Members and units for missions and to help reset and improve resilience between deployments.*

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<sup>7</sup> Intervention repurposing is the identification of novel indication(s) for an FDA-approved intervention.

- *Effective solutions to support relationships and parenting, prepare families for potential secondary trauma exposure, and empower families to access tailored support and resources.*
3. **Treat:** Research will address novel and repurposed interventions<sup>8</sup> to improve outcomes of psychological health conditions and/or TBI. Efforts that address treatment, rehabilitation, and health services research are within scope.
- a. Interventions that promote sustained functional recovery, including interventions administered acutely, during the post-acute phase, or during the chronic phase of injury.
- *Rapid assessments and treatments for psychological health conditions. Interventions addressing adjustment disorders, ASRs, and PTSD may be proposed.*
  - *Mobile health technologies to improve mental health and well-being.*
  - *Interventions focused on sensory and motor dysfunction after brain injury.*
  - *Interventions that address neurodegenerative processes associated with TBI.*
  - *Interventions that restore cognitive reserve and functioning.*
  - *Novel therapeutic candidates based on evolving changes of pathophysiology and/or theoretical mechanisms of psychological health conditions and/or TBI.*
  - *Interventions and/or the delivery of health care services to improve the ability to treat co-occurring TBI and psychological health conditions.*
  - *Personalized medicine approaches to treatment that may include tailoring treatment to the biological and endophenotypic elements present. Treatment approaches may consider how TBI, PTSD, depression, or other psychological health conditions are interrelated.*
  - *Considerations for sequencing and optimal combinations of pharmacologic and non-pharmacologic interventions.*
  - *Effective, early interventions for delivery in rural or other resource-limited environments (e.g., far-forward military environments), and/or by non-clinicians (e.g., peers, teams, first responders/medics).*
- b. Development of postvention strategies to support individuals in workplace or community environments following a sexual assault, suicide event, or other trauma.

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<sup>8</sup> Intervention repurposing is the identification of novel indication(s) for an FDA-approved intervention.

- c. Health services research to improve provider adoption of evidence-based practices, improve access, and reduce barriers. In addition, factors that influence treatment engagement, follow-up care, and improvement of long-term outcomes are of interest.
- *Research of interest includes, but is not limited to individual, peer/unit/team, leader, family, caregivers, community, and enterprise level methods.*
  - *Clinical effectiveness studies comparing emerging capabilities to existing evidence-based treatments and/or the standard of care.*
  - *Identification and evaluation of methods for successful dissemination and implementation of interventions.*