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

Emerging Topics Research Award

Announcement Type: Initial

Funding Opportunity Number: HT942524TBIPHRPETRA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Prepoposal) 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."

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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 Emerging Topics Research Award (ETRA) Topic Areas

To meet the intent of the funding opportunity, applications must address at least one of the FY24 TBIPHRP ETRA Topic Areas below. The Topic Areas align with the TBIPHRP Understand, Prevent/Assess and Treat Strategic Goals described in the TBIPHRP Strategic Plan. Applications consisting solely or primarily of planning, engineering, manufacturing, or formulation activities may be administratively withdrawn. Selection of the appropriate FY24 TBIPHRP ETRA Topic 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. **Blast/Impulse Exposure and Psychological/Cognitive Health:** There has been recent emphasis placed on the unseen wounds of war and brain health deficits seen in Warfighters

returning from combat zones, but with no diagnosable conditions.[1, 2] These Service Members are not experiencing the classical symptoms of traumatic brain injury or the symptoms necessary for a posttraumatic stress disorder (PTSD) diagnosis. If clinical providers probe further, there are clear deficiencies that coincide with chronic impulse exposure and insults to the head, but without a named disorder, it is very difficult to build an effective treatment regimen. There is a need for increased research to understand the mechanisms of how these exposures are affecting the brain physically and increased etiological considerations for how the physical blows manifest to cognitive deficits and psychiatric episodes outside of the International Classification of Diseases paradigm. ***Topic Areas are:***

- o Understand the physiological and molecular mechanisms of hazardous impulse, impact, or blast exposures that result in adverse effects on the brain.

- o Understand changes in cognitive performance and psychological status associated with brain exposure(s).

- o Develop and/or validate safe and effective countermeasures to protect or restore brain health (e.g., cognition or psychological health) in the event of exposure(s).

2. **Diagnosis and Treatment of Anger:** Large survey studies of U.S. (Army Study to Assess Risk and Resilience in Servicemembers — Longitudinal Study [STARRS – LS],[3] Millennium Cohort Study[4]) and Australian military personnel have found that problematic anger is prevalent among Service Members and Veterans.[5, 6] Anger is frequently comorbid with PTSD, and a history of anger attacks is predictive of persistent PTSD and of new onset depression, anxiety, substance use, and suicidality.[7] While anger is listed as a factor to consider in the Department of Veterans Affairs (VA)/DOD Clinical Practice Guidelines for the Assessment and Management of Patients at Risk of Suicide, there are no known guidelines for treating anger and aggression in Service Members and Veterans.[8] A current systematic review of treatments for anger in military populations with PTSD found that PTSD-focused and mind-body treatments were largely ineffective in addressing anger.[9] Given the prevalence and negative impact of problematic anger among military personnel, as

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[1] https://www.nytimes.com/2023/11/26/us/military-brain-injury-rocket-launcher.html
[2] https://www.nytimes.com/2023/11/05/us/us-army-marines-artillery-isis-pentagon.html
[3] https://starrs-ls.org/
[4] https://www.millenniumcohort.org/
[5] Adler AB, LeardMann CA, Roenfeldt KA, et al., and Millennium Cohort Study Team. 2020. Magnitude of problematic anger and its predictors in the Millennium Cohort. BMC Public Health 20:1-11.
[6] Varker T, Cowlishaw S, Baur J, et al. 2022. Problem anger in veterans and military personnel: Prevalence, predictors, and associated harms of suicide and violence. *Journal of Psychiatric Research* 151:57-64.
[7] Metcalf O, Finlayson-Short L, Forbes D, et al. 2023. A systematic review of treatments for problem anger in veteran and military populations with PTSD. Aggression and Violent Behavior 101837.
[8] Department of Veterans Affairs/Department of Defense. 2019. VA/DoD clinical practice guidelines for the assessment and management of patients at risk of suicide.
https://www.healthquality.va.gov/guidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf
[9] https://www.cdc.gov/violenceprevention/about/social-ecologicalmodel.html

well as its association with new onset psychological health issues, more research is needed. ***Topic Areas are:***

o   Developing and evaluating screening and early intervention strategies.

o   Systematizing the measurement and assessment of anger symptoms.

o   Treatment approaches that directly address anger, especially in individuals who have sustained a traumatic brain injury where the experience/expression of anger or aggression/impulsivity may be related, in part, to the biological dysregulation secondary to brain injury.

3. **Define risk and protective factors for harmful behaviors at the interpersonal and organizational levels:** Risk and protective factors for harmful behaviors[10] at the interpersonal and organizational level of the social-ecological model[11] need to be further understood in a military context; most research to date has been contextualized at the individual level. There is a need to better understand protective factors and risk factors that are shared across multiple forms of harmful behaviors. Defining these factors beyond the individual level that align with a military setting and with recommendation 2.3a (implementation of prevention strategies at organizational and community levels) of the Independent Review Commission on Sexual Assault in the Military[12] will set the stage for future studies to identify change over time and program evaluation efforts (focused on modifying those factors) to decrease harmful behaviors. ***Topic Areas are:***

o   Understanding risk, protective, and biological factors beyond the individual level that are shared across multiple forms of harmful behaviors.[10]

o   Research involving collective efficacy is of interest. Community collective efficacy, in which a group perceives an ability to work together to agree on mutually valued goals, is associated with reduced rates of child maltreatment and intimate partner violence.[13, 14, 15]

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[10] Harmful behaviors include adverse outcomes such as sexual assault, suicide, and interpersonal violence (including intimate partner and family violence).
https://www.armyresilience.army.mil/ard/images/pdf/Policy/PPOA%202.O.pdf
[11] https://www.cdc.gov/violenceprevention/about/social-ecologicalmodel.html
[12] Independent Review Commission on Sexual Assault in the Military. 2021. Hard truths and the duty to change: Recommendations from the Independent Review Commission on Sexual Assault in the Military. Independent Review Commission on Sexual Assault in the Military. https://media.defense.gov/2021/Jul/02/2002755437/-1/-1/0/IRC-FULLREPORT-FINAL-1923-7-1-21.PDF
[13] Capaldi DM, Knoble NB, Shortt JW, et al. 2012. A systematic review of risk factors for intimate partner violence. Partner Abuse 3(2):231-280.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3384540/pdf/nihms385813.pdf
[14] Armstead TL, Wilkins N, and Doreson A. 2018. Indicators for evaluating community- and societal-level risk and protective factors for violence prevention: Findings from a review of the literature. *Journal of Public Health Management Practice* 24:S42-S50. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5886365/
[15] Sanchez C, Jaguan D, Shaikh S, et al. 2020. A systematic review of the causes and prevention strategies in reducing gun violence in the United States. American Journal of Emergency Medicine 38(10), 2169-2178.
https://pubmed.ncbi.nlm.nih.gov/33071102/

- o Research involving alcohol outlet density and other community- and societal level risk factors are of interest. Community-level factors such as alcohol outlet density, neighborhood disorder, and firearm availability and accessibility increase risk for harmful behaviors. Examples of societal level risk factors include gender stereotypes and institutionalized racism.[16]

4. **Relationship Between Social Media and Mental Health:** Growing concerns about the relationship between problematic social media use (PSMU) and negative mental health outcomes is gaining public awareness. Calls for action for more research on social media's harms and potential benefits on mental health have been issued by the White House[17] and the U.S. Surgeon General's Office.[18] In a recently conducted systematic review, the Psychological Health Center of Excellence (PHCoE) found a longitudinal association between PSMU and depression, sleep disturbances, and other mental health outcomes in predominantly healthy populations[19]; however, PHCoE found no research on social media use or social media addiction in Service Members. The DOD has similarly prioritized understanding Service Members' activities and prevention needs within the cyber environment to include use of social media platforms and online "information cocoons" (i.e., when a person's cyber experience is shaped by a reflection of the person's own views).[20] *Topic Areas are:*

   - o Understanding how social media use impacts harmful behaviors and adverse mental health outcomes among Service Members.

   - o Examining the role of risk factors and modifiable targets in social media addiction to develop preventive interventions and identifying interventions to treat social media addiction.

II.A.2. Award History

The TBIPHRP ETRA mechanism is being offered for the first time in FY24.

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[16] Armstead TL, Wilkins N, and Doreson A. 2018. Indicators for evaluating community- and societal-level risk and protective factors for violence prevention: Findings from a review of the literature. *Journal of Public Health Management Practice* 24:S42-S50. https://pubmed.ncbi.nlm.nih.gov/33071102/

[17] The White House. (February 2023). White House Report on Mental Health Research Priorities. Retrieved October 27, 2023, from https://www.whitehouse.gov/wp-content/uploads/2023/02/White-House-Report-on-Mental-Health-Research-Priorities.pdf

[18] U.S. Department of Health and Human Services. 2023. Surgeon General Issues New Advisory About Effects Social Media Use Has on Youth Mental Health. https://www.hhs.gov/about/news/2023/05/23/surgeon-general-issues-new-advisory-about-effects-social-media-use-has-youth-mental-health.html

[19] Bellanti DM, Boyd C, Smolenski DJ, et al. 2023. Problematic social media use and mental health: A systematic review of longitudinal studies. [Manuscript submitted for publication].

[20] Office of the Under Secretary of Defense (Personnel and Readiness). 2022. FY23 Integrated Prevention Research Agenda. Retrieved on October 27, 2023, from https://www.prevention.mil/Portals/130/Documents/2023%20Integrated%20Prevention%20Research%20Agenda.pdf?ver=5nWUoNuEExzzlw9Y0GczGA%3D%3D

II.B. Award Information

The FY24 TBIPHRP ETRA intends to accelerate research in emerging topics in traumatic brain injury and/or psychological health. Findings from the FY24 ETRA-funded research should ultimately support the generation of new or updated clinical applications, health care products, and clinical practice guidelines for Service Members, their Families, Veterans, and the American public.

Research Scope: Applications to the FY24 TBIPHRP ETRA may include preclinical applied research (including animal research) and clinical research (including clinical trials). Applications must not include basic research[21]. The FY24 TBIPHRP ETRA 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***.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (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.

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[21] 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.

(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 the 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 ETRA 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 clinical research, or pilot/exploratory clinical trials. The maximum period of performance is 3 years. The application's direct costs budgeted for the entire period of performance should not exceed $700,000.

- **Research Level 2:** Research Level 2 is intended to support larger scope, more complex preclinical, clinical research, or clinical trials. The maximum period of performance is 4 years. The application's direct costs budgeted for the entire period of performance should not exceed $1.5M.

  - **Early-Career Investigator Partnering Option:** The FY24 TBIPHRP ETRA (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 $1.5M.***

- o 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.

- o The intent is not to create 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.

- o If recommended for funding, each PI will be named to an individual award within the recipient organization(s). For individual FY24 TBIPHRP ETRA 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). 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.

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 the 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.

Clinical Trials Involving Psychedelic Interventions and Service Members: 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.

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 ETRA, 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 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**

  o Applicants proposing to conduct research collecting both TBI and psychological health human subject data may follow the guidance for either TBI research, psychological health research, or both as appropriate. Applicants 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 Emerging Topics Research Award should not exceed **$700,000 (Research Level 1) or $1.5M (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 $16.0M to fund approximately four ETRA Research Level 1 applications and five ETRA 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
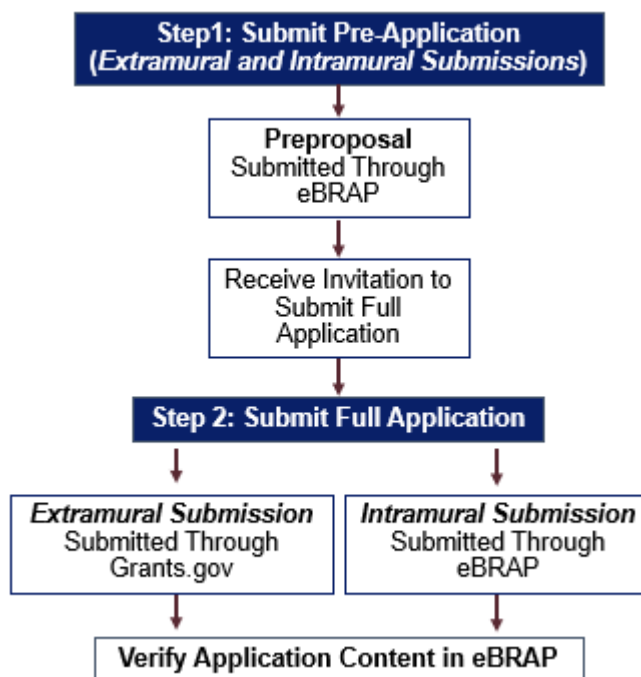
Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524TBIPHRPETRA 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 HT942524TBIPHRPETRA 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 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 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) 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).

The Partnering PI 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:

  o **Topic Area:** Describe how the proposed project is relevant to the selected FY24 TBIPHRP ETRA Topic Area(s).

  o **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 research resources and subject population. As applicable, provide the regulatory status (including device classification) and identify the regulatory sponsor.

  o **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.

  o **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:

  o **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).

  o **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

  o **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:

- **Topic Area:** The degree to which the proposed research is relevant to the selected FY24 TBIPHRP ETRA Topic Area(s).

- **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 the Initiating PI

Research Level 2 Early-Career Investigator Partnering Option: The CDMRP requires separate full application package submissions for the Initiating PI and 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 PI 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 FY24 TBIPHRP ETRA Topic Area(s). 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 ETRA 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.

  - *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 U.S. Department of Veterans Affairs (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.

– **Background:** State how the proposed research addresses one or more FY24 TBIPHRP ETRA Topic 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).

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

- Describe the ultimate applicability of the research and how it addresses the selected FY24 TBIPHRP ETRA Topic Area(s).

- 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, their Families, and/or Veterans.

○ **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 TBIPHR ETRA, 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 for human subjects research

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

– For FITBIR- or NIMH NDA-eligible research should also include the following subtask:

▪ 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 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 lead to advancement in the selected FY24 TBIPHRP ETRA Topic Area(s) and supports the generation of new or updated clinical applications, health care products, and clinical practice guidelines.

▪ 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.

- o **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 research to commercialization or 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 the next logical step of preclinical or clinical research, 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 <u>required</u> 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.

o **Attachment 10: Clinical Strategy Statement (no page limit): Upload as "Clinical.pdf".** *(Attachment 10 is <u>required</u> for applications that propose a clinical trial.)*

For the FY24 TBIPHRP ETRA, 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 clinical trial and the endpoints to be measured. Identify the clinical trial phase.

  - Provide a brief description of the product/intervention(s).

- *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 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 U.S. FDA or international regulatory agency has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.

- ***For the FY24 TBIPHRP ETRA, 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 <u>required</u> 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. Study risks include any risks that the human subject is exposed to as a result of participation in the clinical research/trial. Consider psychological, legal, social, and economic risks as well as physical risks. Consider how the proposed clinical research/trial might affect the daily lives of the individual human subjects participating in the study. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

  - ▪ **Risk management and emergency response:**

    - ❖ Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (if applicable) will be managed and conducted.

    - ❖ Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.

    - ❖ Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.

    - ❖ Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).

    - ❖ Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.

- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

– **Data Management Plan:** Describe 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 those who will have access to study records, data, and specimens, including an acknowledgment that DOD representatives are eligible to review study records.

  ❖ Address requirements for reporting sensitive information to state or local authorities.

- **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For Regulatory Agency oversight, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) are required.

- **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with a Regulatory Agency, if applicable.

- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

- **Laboratory Evaluations:**

  - **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated and relevance to the study objectives described. The collection schedule and amount of material collected must also be clearly described.

  - **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations are relevant to the study objectives (or to monitor safety of human subjects).

  - **Storage:** Describe specimen storage, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use, including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.

  - **Laboratories performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **Questionnaires and Other Research Data Collection Instruments, if applicable:**

  - Provide a copy of the most recent version of 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 an implementation plan for how and when the instrument(s) will be administered.

    - Describe how the instrument(s) will be adapted to the subject population(s), if applicable. If the adaptation results in a deviation from validated instruments, please justify.

o **Attachment 12: Partnership Statement (two-page limit): Upload as "Partnership.pdf".** *(Attachment 12 is only applicable and <u>required</u> for applications submitted under the Early-Career Investigator Partnering Option.)*

– Provide a statement confirming that the Early-Career Investigator meets the <u>eligibility requirements</u>. ***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.

o **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.

o **Attachment 14: Representations** *(Extramural Submissions Only)*: **Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<u>https://ebrap.org/eBRAP/ public/Program.htm</u>). 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.

- o **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- o **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 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 information.

(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 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 **$700,000**. 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 **$1.5M**. 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 **$1.5M**. 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.

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 ETRA.

- **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 ETRA

- Costs associated with CBPR implementation.

- Research subject compensation and reimbursement for 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 FY24 TBIPHRP ETRA Topic Area(s).

  - 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 clinical trial

  ○ 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 lead to advancement in the selected [FY24 TBIPHRP ETRA Topic Area(s)](#) and supports the generation of new or updated clinical applications, health care products, and clinical practice guidelines.

  - 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 criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **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 extent the scientific environment is appropriate for the proposed research project.

  - To what extent the quality and level of institutional support are appropriate for the proposed research 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, 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

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

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 and 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:

- Pre-application was not submitted.

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

- Submission of an application for which a letter of invitation was not issued.

- [Attachment 6](), Impact Statement, is missing.

- [Attachment 7](), Relevance to Miliary 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 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 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.

- The invited application proposes a different research project than that described in the pre-application.

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

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

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

- The PI(s) or Early-Career Investigator do not meet the eligibility criteria.

- Basic research is proposed.

- Application failed to address at least one of the FY24 TBIPHRP ETRA Topic 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).

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
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐	☐
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐	
Statement of Work –Attachment 5, upload as "SOW.pdf"	☐	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐	
Relevance to Military Health Statement – Attachment 7, upload as "Military.pdf"	☐	
Transition Plan – Attachment 8, upload as "Transition.pdf"	☐	
Animal Research Plan *(if applicable)* – Attachment 9, upload as "AnimRschPln.pdf"	☐	
Clinical Strategy Statement *(if applicable)* – Attachment 10, upload as "Clinical.pdf"	☐	
Human Subject Recruitment Safety Procedures *(if applicable)* – Attachment 11, upload as "HumSubProc.pdf"	☐	
Partnership Statement *(if applicable)* – Attachment 12, upload as "Partnership.pdf"	☐	
CBPR Document *(if applicable)* – Attachment 13, upload as "CBPR.pdf"	☐	
Representations *(Extramural submissions only)* – Attachment 14, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental Budget Form *(if applicable)* – Attachment 15, upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐

Full Application Components	Uploaded	
	Single or Initiating PI	**Partnering PI**
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐	☐
Research & Related Budget (*Extramural submissions only*) Include budget justification	☐	☐
Budget (*Intramural submissions only*) Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form (*if applicable)*	☐	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting *In Vivo* Experiments
CAB	Community Advisory Board
CBPR	Community-Based Participatory Research
CDE	Common Data Elements
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
EFIC	Exception from Informed Consent
ET	Eastern Time
ETRA	Emerging Topics Research Award
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
PSMU	Problematic Social Media Use

PTSD	Posttraumatic Stress Disorder
SAM	System for Award Management
SOW	Statement of Work
STARRS-LS	Study to Assess Risk and Resilience in Servicemembers – Longitudinal Study
TBI	Traumatic Brain Injury
TBIPHRP	Traumatic Brain Injury and Psychological Health Research Program
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

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

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

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

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

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

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

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

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