FY24 Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP) Focus Areas

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.

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

Psychedelic clinical trials involving eligible active-duty Service Members are allowed: Section 723 of the National Defense Authorization Act for Fiscal Year 2024 authorizes the DOD to conduct research involving using 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 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.

1. **Understand:** Research will address knowledge gaps in epidemiology and etiology of psychological health conditions and/or traumatic brain injury (TBI).
   a. Understanding of risk, protective, and biological factors contributing to an individual's vulnerability to, response to, and long-term outcomes of psychological health conditions and/or TBI.
   b. Understanding sexual harassment and assault perpetration, victimization, barriers to reporting and response. Studies that ensure participant anonymity are strongly encouraged.

2. **Prevent and Assess:** Research will address the prevention, screening, diagnosis, or prognosis of psychological health conditions and/or TBI.
   a. Identification and validation of biomarkers or other objective methods for assessment, diagnosis, prognosis, or real-time monitoring of psychological health conditions and/or TBI (including subclinical presentations) and associated sequelae of these conditions.
      - *Development of decision-making frameworks or tools that incorporate objective assessments and may consider long-term outcomes to inform return to activity/duty decisions are within scope.*
   b. Development and evaluation of approaches or tools to prevent or reduce risk of psychological health conditions and/or TBI.
      - *Evaluation of environmental sensor data in aspects related to brain health and risk from brain blast and impact exposures.*
      - *Development of innovative materials and technologies that can prevent or reduce risk of TBI.*
      - *Generation of physiological evidence regarding the safety, efficacy, and utility of candidate neuroprotective measures. Animal models, if used, should be validated and well justified within the literature and should demonstrate clear alignment to clinical populations.*
      - *Validation of objective tools/methods for assessing and real-time health status monitoring of psychological health conditions and/or TBI.*
      - *Development of clinical decision-making frameworks or tools that incorporate objective assessments and long-term outcomes to return to activity/duty decisions.*
   c. Development and evaluation of crosscutting prevention approaches to address multiple adverse outcomes such as suicide, interpersonal violence (including intimate partner and family violence), and psychological health issues are within scope.
      - *Optimized messaging for successful dissemination and implementation.*
      - *Inclusion of families[1] and evaluation of family impact.*
      - *Culturally acceptable approaches to reducing access to lethal means and promoting means safety for suicide and violence prevention.*
   d. Development and evaluation of solutions to support military and family readiness and increase psychological resilience in individuals to the potential negative impacts of specific military and life stressors.
      - *Effective pharmacologic or non-pharmacologic prevention interventions. Solutions for prevention of acute stress reactions (ASRs) and PTSD or adjustment disorders may be proposed.*
      - *Preparation of Service Members and units for missions and to help reset and improve resilience between deployments.*

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

3. **Treat:** Research will address novel and repurposed interventions[1] to improve outcomes of psychological health conditions and/or TBI. Efforts that address treatment, rehabilitation, and health services research are within scope.

   a. Interventions that promote sustained functional recovery, including interventions administered acutely, during the post-acute phase, or during the chronic phase of injury.

      - *Rapid assessments and treatments for psychological health conditions. Interventions addressing adjustment disorders, ASRs, and PTSD may be proposed.*
      - *Mobile health technologies to improve mental health and well-being.*
      - *Interventions focused on sensory and motor dysfunction after brain injury.*
      - *Interventions that address neurodegenerative processes associated with TBI.*
      - *Interventions that restore cognitive reserve and functioning.*
      - *Novel therapeutic candidates based on evolving changes of pathophysiology and/or theoretical mechanisms of psychological health conditions and/or TBI.*
      - *Interventions and/or the delivery of healthcare services to improve the ability to treat co-occurring TBI and psychological health conditions.*
      - *Personalized medicine approaches to treatment that may include tailoring treatment to the biological and endophenotypic elements present. Treatment approaches may consider how TBI, PTSD, depression, or other psychological health conditions are interrelated.*
      - *Considerations for sequencing and optimal combinations of pharmacologic and non-pharmacologic interventions.*
      - *Effective, early interventions for delivery in rural or other resource-limited environments (e.g., far-forward military environments), and/or by non-clinicians (e.g., peers, teams, first responders/medics).*

   b. Development of postvention strategies to support individuals in workplace or community environments following a sexual assault, suicide event, or other trauma.

[1] Intervention repurposing is the identification of novel indication(s) for an FDA-approved intervention.

c. Health services research to improve provider adoption of evidence-based practices, improve access, and reduce barriers. In addition, factors that influence treatment engagement, follow-up care, and improvement of long-term outcomes are of interest.

- *Research of interest includes, but not limited to: individual, peer/unit/team, leader, family, caregivers, community, and enterprise level methods.*
- *Clinical effectiveness studies comparing new/novel capabilities to existing evidence-based treatments and/or the standard of care.*
- *Identification and evaluation of methods for successful dissemination and implementation of interventions.*