US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2023 (FY23) TRAUMATIC BRAIN INJURY AND PSYCHOLOGICAL HEALTH RESEARCH PROGRAM (TBIPHRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY23 TBIPHRP called for applications in response to program announcements (PAs) for two award mechanisms released in April 2023:

- Clinical Trial Award
- Focused Program Award

Pre-applications were received for these two PAs in June 2023 and screened in July 2023 to determine which investigators would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the PAs.

Applications were received for these two PAs in September 2023 and peer reviewed in December 2023. Programmatic review was conducted in February 2024.

In response to the Clinical Trial Award PA, 111 pre-applications were received, and the Principal Investigators (PIs) of 73 of these were invited to submit a full application. Sixty-three compliant applications were received, and 39 (61.9%) were recommended for funding, representing 43 total awards, for a total of \$91.63 million (M).

In response to the Focused Program Award PA, 33 pre-applications were received, and the PIs of 18 of these were invited to submit a full application. Fifteen compliant applications were received, and four (26.7%) were recommended for funding for a total of \$26.18M.

Submission and award data for the FY23 TBIPHRP are summarized in the table(s) below.

Mechanism	Pre- Applications Received	Pre- Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Clinical Trial Award [±]	111	73 (65.8%)	63	39 (61.9%; 43 awards)	\$91.63M
Focused Program Award	33	18 (54.5%)	15	4 (26.7%)	\$26.18M
Total	144	91 (63.2%)	78	43 (55.1%; 47 awards)	\$117.81M

Table 1. Submission/Award Data for the FY23 TBIPHRP*

*These data reflect funding recommendations only. Pending FY23 award negotiations, final numbers will be available after September 30, 2024.

[±]The Clinical Trial Award had an Early-Career Investigator Partnering Option. The Clinical Trial Award had 39 applications recommended for funding, representing 43 total awards.

Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Understand—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.	5	3 (60.0%)	\$19.88M
Understand—Understanding sexual harassment and assault prevention, perpetration, victimization, and response.	2	2 (100.0%)	\$3.28M
Prevent/Assess—Identification and validation of biomarkers or other objective markers for diagnosis, prognosis, or monitoring of psychological health conditions and/or TBI, repetitive exposures, and associated sequelae (e.g., chronic migraine, dizziness, neurocognitive symptoms, sleep, post- traumatic headache, secondary complications)	9	3 (33.3%)	\$9.86M
Prevent/Assess—Approaches or tools to prevent or reduce risk of psychological health conditions and/or TBI.	8	3 (37.5%)	\$5.81M
Prevent/Assess—Development of injury thresholds and exposure standards for TBI.	1	0 (0.00%)	\$0.00M
Prevent/Assess—Development, evaluation, and implementation of crosscutting prevention approaches targeting upstream factors or leveraging communities and peers to address multiple adverse outcomes such as suicide, multiple forms of violence, and alcohol and substance use disorders.	6	6 (100.0%)	\$16.58M
Prevent/Assess—Development of solutions to increase readiness and psychological resilience in individuals, small teams, families1, and communities to ameliorate the potential negative impacts of specific military and life stressors.	2	1 (50.0%)	\$0.78M
Prevent/Assess—Development of solutions to address aspects of workplace culture and climate (e.g., leadership	0	0 (0.00%)	\$0.00M

Table 2. FY23 TBIPHRP Application Data by Focus Area

Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
attitudes, group characteristics, group identification factors) that are associated with increases in harmful behaviors.			
Treat—Interventions that promote sustained functional recovery, including interventions administered acutely, during the post-acute phase, or during the chronic phase of injury.	41	23 (56.1%)	\$58.53M
Treat—Validated methods for reducing barriers to care for psychological health conditions and/or TBI challenges (e.g., PTSD, suicidal ideation or behaviors, alcohol and substance use, anxiety, depression) and informing processes that lead to increases in help-seeking behavior.	3	1 (33.3%)	\$0.67M
Treat—Implementation, follow-up, and services research to increase provider adoption and availability of evidence- based treatments, as well as treatment engagement, follow-up care, and understanding of long-term outcomes.	1	1 (100.0%)	\$2.41M
Treat—Effective postvention strategies to address social connectedness during reintegration of individuals into workplace or community environments following a sexual assault, suicide event, or other severe trauma.	0	0 (0.00%)	\$0.00M
Totals	78	43	\$117.80M

THE TWO-TIER REVIEW SYSTEM

The USAMRDC developed a review model based on recommendations of the 1993 Institute of Medicine (IOM) (now called the National Academy of Medicine) of the National Academy of Sciences report, *Strategies for Managing the Breast Cancer Research Program: A Report to the Army Medical Research and Development Command.* The IOM report recommended a two-tier review process and concluded that the best course would be to establish a peer review system that reflects not only the traditional strengths of existing peer review systems, but also is tailored to accommodate program goals. The Command has adhered to this proven approach for evaluating competitive applications. An application must be favorably reviewed by both levels of the two-tier review system to be funded.

THE FIRST TIER—Scientific Peer Review

Clinical Trial Award applications were peer reviewed on site in November 2023 by five panels totaling 72 researchers and clinicians, as well as 10 consumer advocates, based on the evaluation criteria specified in the PA. Focused Program Award applications were peer reviewed on site in November 2023 by four panels totaling 54 researchers and clinicians, as well as 8 consumer advocates, based on the evaluation criteria specified in the PA.

Each peer review panel included a Chair, an average of four scientific reviewers, five clinicianscientists reviewers, two consumer reviewers, two biostatistician reviewers, one tech transfer reviewer, one bioethicist reviewer, and a nonvoting Scientific Review Officer. The primary responsibility of the panelists was to review the technical merit of each application based upon the evaluation criteria specified in the relevant PA.

Individual Peer Review Panels

The Chair for each panel presided over the deliberations. Applications were discussed individually. The Chair called upon the assigned reviewers for an assessment of the merits of each application using the evaluation criteria published in the appropriate PA. Following a panel discussion, the Chair summarized the strengths and weaknesses of each application, and the panel members then rated the applications confidentially.

Application Scoring

Evaluation Criteria Scores: Panel members were asked to rate each peer review evaluation criterion as published in the appropriate PA. A scale of 1 to 10 was used, with 1 representing the lowest merit and 10 the highest merit, using whole numbers only. The main reasons for obtaining the criteria ratings were to (1) place emphasis on the published evaluation criteria and provide guidance to reviewers in determining an appropriate overall score and (2) provide the applicant, the Programmatic Panel, and the Command with an informed measure of the quality regarding the strengths and weaknesses of each application. The evaluation criteria scores were not averaged or mathematically manipulated in any manner to connect them to the global or percentile scores.

Overall Score: To obtain an overall score, a range of 1.0 to 5.0 was used (1.0 representing the highest merit and 5.0 the lowest merit). Reviewer scoring was permitted in 0.1 increments. Panel member scores were averaged and rounded to arrive at a two-digit number (1.2, 1.9, 2.7, etc.). The following adjectival equivalents were used to guide reviewers: Outstanding (1.0–1.5), Excellent (1.6–2.0), Good (2.1–2.5), Fair (2.6–3.5), and Deficient (3.6–5.0).

Summary Statements: The Scientific Review Officer on each panel was responsible for preparing a Summary Statement reporting the results of the peer review for each application. The Summary Statements included the evaluation criteria and overall scores, peer reviewers' written comments, and the essence of panel discussions. This document was used to report the peer review results to the Programmatic Panel. It is the policy of the USAMRDC to make Summary Statements available to each applicant when the review process has been completed.

THE SECOND TIER—Programmatic Review

Programmatic review was conducted in February 2024 by the FY23 Programmatic Panel, which was comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in TBI or psychological health. Programmatic review is a comparison-based process that considers scientific evaluations across all disciplines and specialty areas. Programmatic Panel members do not automatically recommend funding applications that were highly rated in the technical merit review process; rather, they carefully scrutinize applications to allocate the limited funds available to support each of the award mechanisms as wisely as possible. Programmatic review criteria published in the Clinical Trial Award and Focused Program Award PAs were as follows: ratings and evaluations of the scientific peer review panels; adherence to the intent of the award mechanism; program portfolio composition; relative impact and military benefit. After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.