US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2023 (FY23) TOXIC EXPOSURES RESEARCH PROGRAM (TERP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY23 TERP called for applications in response to program announcements (PAs) for three award mechanisms released in July 2023:

- Clinical Trial Award
- Investigator-Initiated Research Award
- Translational Research Award

Letters of Intent were received for these three PAs in September 2023.

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

In response to the Clinical Trial Award PA, 11 compliant applications were received and two (18.2%), representing four awards, were recommended for funding for a total of $6.5 million (M).

In response to the Investigator-Initiated Research Award PA, 134 compliant applications were received and eight (6.0%) were recommended for funding for a total of $5.8M.

In response to the Translational Research Award PA, 49 compliant applications were received and six (12.2%), representing 13 awards, were recommended for funding for a total of $14.1M.

Submission and award data for the FY23 TERP are summarized in the tables below.

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

Topic Area	Compliant Applications Received†	Applications Recommended for Funding (%)†	Total Funds
Clinical Trial Award	11 applications representing 18 potential awards	2 (18.2%) applications representing 4 awards	$6.5M
Investigator-Initiated Research Award	134	8 (6.0%)	$5.8M
Translational Research Award	49 applications representing 93 potential awards	6 (12.2%) applications representing 13 awards	$14.1M
Totals	**194 applications representing 245 potential awards**	**16 (8.2%) applications representing 25 awards**	**$26.4M**

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

†The Translational Research Award and Clinical Trial Award offered a Partnering Principal Investigator Option.

Table 2. FY23 TERP Application Data by Topic Area

Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Neurotoxin Exposure	38 applications representing 44 awards	3 (7.9%) applications representing 4 awards	$3.8M
Gulf War Illness and Its Treatment	31 applications representing 38 awards	4 (12.9%) applications representing 6 awards	$6.3M
Airborne Hazards and Burn Pits	48 applications representing 69 awards	5 (10.4%) applications representing 10 awards	$10.8M
Other Military Service-Related Toxic Exposures in General, Including: Prophylactic Medications, Pesticides, Organophosphates, Toxic Industrial Chemicals, Materials, Metals, and Minerals	77 applications representing 94 awards	4 (5.2%) applications representing 5 awards	$5.5M
Totals	**194 applications representing 245 awards**	**16 (8.2%) applications representing 25 awards**	**$26.4M**

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, Investigator-Initiated Research Award, and Translational Research Award applications were peer reviewed in December 2023 by 14 panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

Peer review was conducted via videoconference for the Investigator-Initiated Research Award, Translational Research Award, and Clinical Trial Award. Each peer review panel included a Chair, an average of eight scientific reviewers, an average of two consumer reviewers, a nonvoting Scientific Review Officer, a biostatistician, a technology transfer specialist for Translational Research Awards and Clinical Trial Awards and a bioethicist for Clinical Trial Awards. 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 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 that was comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in toxic exposures. 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 PAs were as follows: ratings and evaluations of the peer reviewers; relevance to the mission of the Defense Health Program and FY23 TERP, as evidenced by the following: adherence to the intent of the award mechanism; program portfolio composition and balance; relative impact (or clinical impact for the Clinical Trial Award) and

relevance to military health. After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.