US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2023 (FY23) NEUROFIBROMATOSIS RESEARCH PROGRAM (NFRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY23 NFRP called for applications in response to program announcements (PAs) for eight award mechanisms released in May 2023:

- Clinical Trial Award (CTA)
- Early-Investigator Research Award (EIRA)
- Exploration – Hypothesis Development Award (EHDA)
- Investigator-Initiated Research Award (IIRA)
- New Investigator Award (NIA)
- Synergistic Idea Award (SIA)
- Neurofibromatosis Research Academy – Leadership Award (NFRA-LA)
- Neurofibromatosis Research Academy – Scholar Award (NFRA-SA)

Pre-applications (letters of intent) were received for all PAs except the NFRA-LA mechanism in September 2023.

Applications were received for the CTA, EIRA, EHDA, IIRA, NIA, and SIA PAs in October 2023 and peer reviewed in November 2023. Programmatic review was conducted in February 2024.

In response to the CTA PA, one compliant application was received, and one was recommended for funding for a total of $1.36 million (M).

In response to the EIRA PA, four compliant applications were received, and one was recommended for funding for a total of $0.30M.

In response to the EHDA PA, 14 compliant applications were received, and 4 were recommended for funding for a total of $0.60M.

In response to the IIRA PA, 30 compliant applications were received, and 7 were recommended for funding for a total of $5.43M.

In response to the NIA PA, 17 compliant applications were received, and 4 were recommended for funding for a total of $2.42M.

In response to the SIA PA, 10 compliant applications (representing 25 potential awards) were received, and 3 were recommended for funding for a total of $8.66M.

In response to the NFRA-SA PA, four compliant applications were received. Due to the lack of receipt of NFRA-LA applications, NFRA-SA full applications could not progress to the review stage and therefore were not eligible for funding.

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

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

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Clinical Trial Award	3	N/A	1	1 (100.00%)	$1.36M
Early Investigator Research Award	4	N/A	4	1 (25.00%)	$0.30M
Exploration-Hypothesis Development Award	18	N/A	14	4 (28.57%)	$0.60M
Investigator-Initiated Research Award	31	N/A	30	7 (23.33%)	$5.43M
New Investigator Award	22	N/A	17	4 (23.53%)	$2.42M
Synergistic Idea Award	13	N/A	10**	3 (30.00%)**	$8.66M
Total	**91**		**76**	**20 (26.32%)**	**$18.77M**

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

**Ten compliant applications received representing 25 potential awards and 3 applications recommended for funding representing 7 potential awards.

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

The CTA, EIRA, EHDA, IIRA, NIA, and SIA applications were peer reviewed in November 2023 via a videoconference by five panel(s) comprised of 39 scientists and 8 consumer advocates based on the evaluation criteria specified in the PAs.

Each peer review panel included a Chair, an average of eight scientific reviewers, an average of two consumer reviewers, 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 essence of the 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 neurofibromatosis. 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. The programmatic review criteria published in the PAs were as follows: ratings and evaluations of the scientific peer review panels; programmatic relevance; relative impact; program portfolio composition; and adherence to the intent of the award mechanism. After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.