

**US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC)
 CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
 FISCAL YEAR 2018 (FY18) DUCHENNE MUSCULAR DYSTROPHY
 RESEARCH PROGRAM (DMDRP)**

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY18 DMDRP called for applications in response to Program Announcements (PAs) for two award mechanisms released in June 2018:

- Career Development Award
- Investigator-Initiated Research Award

Letters of Intent (LOIs) were received for the Career Development Award PA in November 2018. Pre-applications were received for the Investigator-Initiated Research Award PA in August 2018 and screened in September 2018 to determine which investigators would be invited to submit a full application. Pre-applications for the Investigator-Initiated Research Award were screened based on the evaluation criteria specified in the PA.

Applications were received for the Career Development Award PA and the Investigator-Initiated Research Award PA in December 2018 and peer reviewed in February 2019. Programmatic review was conducted in April 2019.

In response to the Career Development Award PA, 12 LOIs were received. Six compliant applications were received, and 0 (0%) were recommended for funding.

In response to the Investigator-Initiated Research Award PA, 68 pre-applications were received, and the PIs of 21 of these were invited to submit a full application. Twenty-one (20) compliant applications were received, and 3 (15%) were recommended for funding for a total of \$2.94 million.

Submission and award data for the FY18 DMDRP are summarized in the table below.

Table 1. Submission/Award Data for the FY18 DMDRP*

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Career Development Award (LOI)	N/A	N/A	6	0 (0%)	\$0
Investigator-Initiated Research Award	68	21 (31%)	20	3 (15%)	\$2,940,221
Total	68	21 (31%)	26	3 (15%)	\$2,940,221

*These data reflect funding recommendations only. Pending FY18 award negotiations, final numbers will be available after September 30, 2019.

THE TWO-TIER REVIEW SYSTEM

The USAMRMC developed a review model based on recommendations of the 1993 Institute of Medicine (IOM) 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 not only reflects 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

Career Development Award and Investigator-Initiated Research Award applications were peer-reviewed via teleconference in February 2019 by two panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

Each peer review panel included a Chair, scientific reviewers, 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 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 applicants' abstracts, the evaluation criteria and overall scores, the peer

reviewers' written comments, and the 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 USAMRMC 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 April 2019 by the FY18 Programmatic Panel, which is comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in Duchenne muscular dystrophy. 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 scientific peer review panels; programmatic relevance; relative impact; program portfolio composition; and adherence to the intent of the award mechanism. After programmatic review, the Commanding General, USAMRMC, and the Director of the Defense Health Agency Research and Development Directorate approved funding for the applications recommended during programmatic review.