US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2020 (FY20) MULTIPLE SCLEROSIS RESEARCH PROGRAM (MSRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY20 MSRP called for applications in response to program announcements (PAs) for three award mechanisms released in April 2020:

- Clinical Trial Award (CTA)
- Exploration – Hypothesis Development Award (EHDA)
- Investigator-Initiated Research Award (IIRA)

Pre-applications were received for these three PAs in June 2020 and screened in July 2020 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 in October 2020 and peer reviewed in December 2020. Programmatic review was conducted in February 2021.

In response to the CTA PA, 37 pre-applications were received and the Principal Investigators (PIs) of 21 of these were invited to submit a full application. Seventeen (17) compliant applications were received and 2 (11.8%) were recommended for funding for a total of $4.33 million (M).

In response to the EHDA PA, 85 pre-applications were received and the PIs of 36 of these were invited to submit a full application. Thirty-three (33) compliant applications were received and 8 (24.2%) were recommended for funding for a total of $1.78M.

In response to the IIRA PA, 101 pre-applications were received and the PIs of 50 of these were invited to submit a full application. Forty-five (45) compliant applications were received and 9 (20.0%) were recommended for funding for a total of $8.04M.

Submission and award data for the FY20 MSRP are summarized in the table below.

Table 1. Submission/Award Data for the FY20 MSRP*

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
CTA	37	21 (56.8%)	17	2 (11.8%)	$4.33M
EHDA – Established Investigator	65	21 (32.3%)	18	3 (16.7%)	$0.59M
EHDA – New Investigator	20	15 (75.0%)	15	5 (33.3%)	$1.19M
IIRA	101	50 (49.5%)	45	9 (20.0%)	$8.04M
Total	**223**	**107 (48.0%)**	**95**	**19 (20%)**	**$14.15M**

*These data reflect funding recommendations only. Pending FY20 award negotiations, final numbers will be available after September 30, 2021.

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

CTA, EHDA, and IIRA applications were peer reviewed in December 2020 by five panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

Peer review for the CTA was conducted by one panel (18 scientific reviewers and 2 consumer reviewers) via teleconference.

Peer review for the EHDA was conducted by two panels (24 scientific reviewers and 4 consumer reviewers) via teleconference.

Peer review for the IIRA was conducted by two panels (19 scientific reviewers and 4 consumer reviewers) via teleconference.

Each peer review panel included a Chair, an average of 12 scientific reviewers, an average of 2 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 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 2021 by the FY20 Programmatic Panel, comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in multiple sclerosis. 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; adherence to the intent of the award mechanism; program portfolio composition; relative impact and innovation[1]; and programmatic relevance to at least one of the MSRP FY20 CTA Focus Areas[2]. After programmatic review, the Commanding General, USAMRDC, and the Director of the Defense Health Agency J9, Research and Development Directorate approved funding for the applications recommended during programmatic review.

[1] Innovation is a criterion of the EHDA only.

[2] Programmatic relevance to at least one of the MSRP FY20 CTA Focus Areas is a criterion of the CTA only.