

**US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
 CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
 FISCAL YEAR 2019 (FY19) JOINT PROGRAM COMMITTEE 8/CLINICAL AND
 REHABILITATIVE MEDICINE RESEARCH PROGRAM (JPC-8/CRM RP)
 RESEARCH PROGRAM**

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY19 JPC-8/CRM RP called for applications in response to a program announcement (PA) for one award mechanism released in June 2019:

- Regenerative Medicine Focused Research Award (RMFRA)

Pre-applications were received for this PA in August 2019 and screened in September 2019 to determine which investigators would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the PA.

Applications were received for this PA in November 2019 and peer reviewed in January 2020. Programmatic review was conducted in March 2020.

In response to the RMFRA PA, 55 pre-applications were received, and the Principal Investigators (PIs) of 18 of these were invited to submit a full application. Fifteen compliant applications were received, and four (27%) were recommended for funding or partial funding for a total of \$19.9 million (M).

Submission and award data for the FY19 JPC-8/CRM RP are summarized in the table(s) below.

Table 1. Submission/Award Data for the FY19 JPC-8/CRM RP RMFRA *

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Recommended Budget
RMFRA	55	18 (33%)	15 [†]	4 [†] (27%)	\$19.9M

*These data reflect funding recommendations only. Pending FY19 award negotiations, final numbers will be available after September 30, 2020. [†] Fifteen and four applications representing 43 and 7 projects, respectively.

Table 2. Submission/Award Data for the FY19 JPC-8/CRM RP RMFRA by Focus Area

Topic Area	Compliant Applications	Applications Recommended for Funding (%)	Recommended Budget
Peripheral Nerve Regeneration	10	2 (20%)	\$10.1 M
Muscle Regeneration	5	2 (40%)	\$9.8 M
Total	15[†]	4[†] (30%)	\$19.9M

[†] Fifteen and four applications representing 43 and 7 projects, respectively.

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 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

RMFRA applications were peer reviewed in January 2020 by two panel(s) of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PA.

Peer review for the RMFRA was conducted by two panels during an on-site meeting. Across these two panels were 30 scientists and 6 consumer reviewers.

Each peer review panel included a Chair, an average of 14 scientific reviewers, an average of 3 consumer reviewers, and a nonvoting Scientific Review Officer. The primary responsibility of the panelists was to review the technical merit of each application based on 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. For each application, the overall research plan was described first, followed by a review of each individual research project. The Chair called on the assigned reviewers for an assessment of the merits of each research project using the evaluation criteria published in the PA for the appropriate application component (i.e., advanced preclinical research project, clinical trial, or overall research plan). Following a panel discussion, the Chair summarized the strengths and weaknesses of each research project, and panel members then rated the research projects confidentially. Once each research project was rated individually for an application, the overall research plan was discussed and rated as a whole.

Application Scoring

Evaluation Criteria Scores: Panel members were asked to rate each peer review evaluation criterion as published in the PA for the appropriate application component. 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 for each application component, 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 component. The evaluation criteria scores were not averaged or mathematically manipulated in any manner to connect them to the global 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). An overall score was provided for each application component.

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 panel discussions for each application component. 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 March 2020 by the FY19 Programmatic Panel, which is comprised of a diverse group of basic and clinical scientists, each contributing special expertise or interest in regenerative medicine. 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 PA was as follows: ratings and evaluations of the scientific peer reviewers; adherence to the intent of the award mechanism, program portfolio composition; programmatic relevance to one or both of the FY19 JPC-8/CRM RP RMFRA Focus Areas; relative impact and military relevance; and relative value in budget. After programmatic review, the Commanding General, USAMRDC, and the Director of the Defense Health Agency J9, Research and Development Directorate, approves funding for the applications recommended during programmatic review.