

**U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)  
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)  
FISCAL YEAR 2019 (FY19) SPINAL CORD INJURY RESEARCH PROGRAM (SCIRP)**

**DESCRIPTION OF REVIEW PROCEDURES**

The programmatic strategy implemented by the FY19 SCIRP called for applications in response to program announcements (PAs) for four award mechanisms released in April 2019:

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

Pre-applications were received for the Clinical Trial Award, Translational Research Award, and Investigator-Initiated Research Award in May 2019 and screened in June – July 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 PAs.

Pre-applications (letters of intent) for the Expansion Award were received in July 2019.

Applications were received for these four PAs in August 2019 and peer reviewed in October 2019. Programmatic review was conducted in January 2020.

In response to the Clinical Trial Award PA, 37 pre-applications were received and the Principal Investigators (PIs) of 23 of these were invited to submit a full application. Nineteen compliant applications were received and two (10.5%) were recommended for funding for a total of \$7.44 million (M).

In response to the Translational Research Award PA, 32 pre-applications were received and the PIs of 19 of these were invited to submit a full application. Fourteen compliant applications were received and five (35.7%) were recommended for funding for a total of \$8.71M.

In response to the Investigator-Initiated Research Award PA, 114 pre-applications were received and the PIs of 76 of these were invited to submit a full application. Seventy-one compliant applications were received and nine (12.7%) were recommended for funding for a total of \$6.36M.

In response to the Expansion Award PA, 34 letters of intent were received, 23 compliant applications were received, and 3 (13.0%) were recommended for funding for a total of \$3.81M.

Submission and award data for the FY19 SCIRP are summarized in the table below.

**Table 1. Submission/Award Data for the FY19 SCIRP\***

<b>Mechanism</b>	<b>Pre-Applications Received</b>	<b>Pre-Applications Invited (%)</b>	<b>Compliant Applications Received</b>	<b>Applications Recommended for Funding (%)</b>	<b>Total Funds</b>
Clinical Trial Award	37	23 (62.2%)	19	2 (10.5%)	\$7.44M
Translational Research Award	32	19 (59.4%)	14	5 (35.7%)	\$8.71M
Investigator-Initiated Research Award	114	76 (66.7%)	71	9 (12.7%)	\$6.36M
Expansion Award	N/A	N/A	23	3 (13.0%)	\$3.81M
<b>Total</b>	<b>183</b>	<b>118 (64.5%)</b>	<b>127</b>	<b>19 (15.0%)</b>	<b>\$26.32M</b>

\*These data reflect funding recommendations only. Pending FY19 award negotiations, final numbers will be available after September 30, 2020.

## **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, Translational Research Award, Investigator Initiated Research Award, and Expansion Award applications were peer reviewed in October 2019 by five panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs. Peer review was conducted by five panels during an on-site meeting. Across these five panels were 62 scientists and 13 consumer reviewers.

Each peer review panel included a Chair, an average of 9 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 January 2020 by the FY19 Programmatic Panel, comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in spinal cord injury. 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; relevance to military health, and adherence to the intent of the award mechanism. 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.