

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

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY19 PH/TBI JPC-8/CRM RP called for applications in response to program announcements (PAs) for two award mechanism released in July 2019:

- Clinical Research Award (CRA)
- Clinical Trial Award (CTA)

Pre-applications were received for this PA in September 2019 and screened in October 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 December 2019 and peer reviewed in January 2020. Programmatic review was conducted in March 2020.

In response to the CRA PA, 27 pre-applications were received and the Principal Investigators (PIs) of 19 of these were invited to submit a full application. Sixteen (16) compliant applications were received and 1 (6.25%) was recommended for funding for a total of \$1.99 million (M).

In response to the CTA PA, 24 pre-applications were received and the PIs of 14 of these were invited to submit a full application. Eleven (11) compliant applications were received and 4 (36.4%) were recommended for funding for a total of \$12.11M.

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

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

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
CRA	27	19 (70.4%)	16	1 (6.25%)	\$1.99M
CTA	24	14 (58.3%)	11	4 (36.4%)	\$12.11M
Total	51	33 (64.7%)	27	5 (18.5%)	\$14.11M

*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

CRA and CTA applications were peer reviewed in January 2020 by a panel of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PA.

Peer review for the CRA and CTA was conducted by two panel(s) during an on-site meeting. Across these two panels were 26 scientists and 2 consumer reviewers.

Each peer review panel included a Chair, an average of two scientific reviewers, an average of one consumer reviewer, 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 April 2020, by the FY19 Programmatic Panel, which was comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in PH/TBI JPC-8/CRM RP. 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 to the mission of the DHP, JPC-8/CRM RP, and PH/TBIRP, as evidence by; relative impact and military relevance; program portfolio composition; 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.