

**DEFENSE HEALTH PROGRAM
 DEFENSE MEDICAL RESEARCH AND DEVELOPMENT PROGRAM
 FISCAL YEAR 2019 (FY19)
 CLINICAL RESEARCH INTRAMURAL INITIATIVE (CRII)
 INVESTIGATOR-INITIATED RESEARCH AWARD (IIRA)**

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY19 CRII called for applications in response to a program announcement (PA) released in February 2019.

Pre-applications were received for this PA and screened in May 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 July 2019 and peer reviewed in October 2019. Programmatic review was conducted in November 2019.

In response to the CRII IIRA PA, 45 compliant applications were received and 7 (15.5%) were recommended for funding for a total budget of \$5,111,471.

Submission and award data are summarized in Tables 1 and 2.

Table 1. Submission/Award Data for the FY19 CRII IIRA *

| Pre-Applications Received | Pre-Applications Invited (%) | Compliant Applications Received | Applications Recommended for Funding (%) | Total Funds |
|----------------------------------|-------------------------------------|--|---|--------------------|
| 101 | 52 (51.4%) | 45 | 7 (15.5%) | \$5,111,471 |

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

Table 2. FY19 IIRA Application Data by Focus Area

| IIRA Focus Area | Compliant Applications Received | Applications Recommended for Funding (%) | Total Funds |
|---|--|---|--------------------|
| Clinical and Rehabilitative Medicine | 5 | 1 (20%) | \$750,000 |
| Combat Casualty Care | 12 | 2 (16.7%) | \$1,379,112 |
| Medical Simulation and Information Sciences | 1 | 1 (100%) | \$744,219 |
| Military Infectious Diseases | 7 | 2 (28.6%) | \$1,488,140 |
| Military Operational Medicine | 16 | 1 (6.3%) | \$750,000 |
| Radiation Health Effects | 4 | 0 (0%) | \$0 |
| Total | 45 | 7 (15.5%) | \$5,111,471 |

THE TWO-TIER REVIEW SYSTEM

The USAMRDC developed a review model based on recommendations of the 1993 Institute of Medicine (IOM) (now known as 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

CR II IIRA applications were peer reviewed in October 2019 by seven panels of researchers and clinicians based on the evaluation criteria specified in the 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 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 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 reviewers, 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, peer reviewers' written comments, and the essence of panel discussions. This document was used to report the peer review results to the programmatic reviewers. 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 November 2019 by a panel comprising researchers and clinicians from the Department of Defense. Programmatic review is a comparison-based process that considers scientific evaluations across all disciplines and specialty areas. Programmatic review panels do not automatically recommend funding applications that were highly rated in the technical merit review process; rather, they carefully weigh all applications to develop recommendations for allocation of the limited funds available. The following equally considered criteria, published in the CRII IIRA PA, were used to make funding recommendations: ratings and evaluations of the scientific peer review panels; and relevance to the mission of the Defense Health Program and FY19 CRII evidenced by adherence to the intent of the award mechanism; program portfolio composition; programmatic relevance to the FY19 CRII IIRA Focus Areas; and relative military benefit and impact. After programmatic review, the Director of the Defense Health Agency J9 Research and Development Directorate and the Office of the Assistant Secretary of Defense for Health Affairs approved funding for the applications recommended during programmatic review.