US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2023 (FY23) PEER REVIEWED ORTHOPAEDIC RESEARCH PROGRAM (PRORP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY23 PRORP called for applications in response to program announcements (PAs) for three award mechanisms released in April 2023:

- Applied Research Award (ARA)
- Clinical Trial Award (CTA)
- Clinical Translation Research Award (CTRA)

Pre-applications were received for these three PAs in June 2023 and screened in July 2023 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.

In response to the ARA PA, 84 pre-applications were received, and the Principal Investigators (PIs) of 60 of these were invited to submit a full application. Fifty-one compliant applications were received, and four (7.8%) were recommended for funding for a total of $3.00 million (M).

In response to the CTRA PA, 64 pre-applications were received, and the PIs of 44 of these were invited to submit a full application. Forty-one compliant applications were received, and six (14.6%) were recommended for funding for a total of $8.37M.

In response to the CTA PA, 35 pre-applications were received, and the PIs of 23 of these were invited to submit a full application. Eighteen compliant applications were received, and five (27.8%) were recommended for funding for a total of $12.87M.

Submission and award data for the FY23 PRORP are summarized in the table(s) below.

Table 1. Submission/Award Data for the FY23 PRORP*

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
ARA	84	60 (71.4%)	51	4 (7.8%)	$3.00M
CTRA	64	44 (68.8%)	41	6 (14.6%)	$8.37M
CTA	35	23 (65.7%)	18	5 (27.8%)	$12.87M
Total	**183**	**127 (69.4%)**	**110**	**15 (13.6%)**	**$24.24M**

*These data reflect funding recommendations only. Pending FY23 award negotiations, final numbers will be available after September 30, 2024.

Table 2. FY23 PRORP Application Data by Focus Area

Topic Area	Compliant Applications	Applications Recommended for Funding (%)	Recommended Budget
Limb Stabilization and Protection	9	1 (11.1%)	$0.75M
Retention Strategies-Battlefield Care	5	1 (20.0%)	$2.50M
Retention Strategies-Return to Duty	50	5 (10.0%)	$9.44M
Osseointegration	11	1 (9.1%)	$1.23M
Composite Tissue Regeneration	16	2 (12.5%)	$1.50M
Translation of Early Research Findings-Soft Tissue Trauma	3	1 (33.3%)	$2.98M
Translation of Early Research Findings-Fracture Related Infection	3	0 (0.0%)	$0.00M
Prostheses and Orthoses	13	4 (30.8%)	$5.84M
Volumetric Muscle Loss	0	0 (0.00%)	$0.00M
Total	**110**	**15 (13.6%)**	**$24.24M**

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

ARA, CTA, and CTRA applications were peer reviewed in November 2023 by panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

Peer review was conducted for the ARA, CTA, and CTRA by seven panels during an on-site meeting. Across these seven panels, 91 were scientists/clinicians/specialists and 12 were consumer reviewers.

Each peer review panel included a Chair, an average of 13 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 on 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 the 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, the peer reviewers' written comments, and the essence of the 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 2024 by the FY23 PRORP Programmatic Panel, which is comprised of a diverse group of pre-clinical and clinical scientists, clinicians, federal and military stakeholders, and consumer advocates, each contributing special expertise or interest in orthopaedic injures and research. 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. The programmatic review criteria published in the PAs were as follows: ratings and evaluations of the scientific peer review panels; programmatic relevance; relative clinical and military impact; program portfolio composition; adherence to the intent of the award mechanism; and regulatory and developmental risk (CTA only). After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.