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

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY23 PRMRP called for applications in response to program announcements (PAs) for five award mechanisms released in January 2023:

- Clinical Trial Award (CTA)
- Focused Program Award (FPA)
- Investigator-Initiated Research Award (IIRA)
- Lifestyle and Behavioral Health Interventions Research Award (LBIRA)
- Technology/Therapeutic Development Award (TTDA)

Pre-applications were received for the FY23 PRMRP CTA and FPA PAs in April 2023 and screened in May–June 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. Applications were received for these two PAs in July 2023 and peer reviewed in September 2023. Programmatic review was conducted in November 2023.

In response to the FY23 PRMRP CTA PA, 165 pre-applications were received and the principal investigators (PIs) of 117 of these were invited to submit a full application. One hundred and nine (109) compliant applications were received and 13 (11.9%) were recommended for funding for a total of $40.1 million (M).

In response to the FY23 PRMRP FPA PA, 60 pre-applications were received and the PIs of 43 of these were invited to submit a full application. Thirty-nine (39) compliant applications were received and 3 (7.7%) were recommended for funding for a total of $26.4M.

Applications were received for the IIRA, LBIRA, and TTDA PAs in May 2023 and peer reviewed in July–August 2023. Programmatic review was conducted in November 2023.

In response to the FY23 PRMRP IIRA PA, 539 compliant applications were received and 40 (7.4%) were recommended for funding for a total of $105.9M.

In response to the FY23 PRMRP LBIRA PA, 40 compliant applications were received and 5 (12.5%) were recommended for funding for a total of $14.9M.

In response to the FY23 PRMRP TTDA PA, 233 compliant applications were received and 30 (12.9%) were recommended for funding for a total of $106.3M.

Submission and award data for the FY23 PRMRP are summarized in the tables below.

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

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
CTA	165	117 (70.9%)	109	13 (11.9%)	$40.1M
FPA	60	43 (71.7%)	39	3 (7.7%)	$26.4M
IIRA	N/A	N/A	539 representing 732 potential awards	40 representing 62 potential awards (7.42%)	$105.9M
LBIRA	N/A	N/A	40	5 (12.5%)	$14.9M
TTDA	N/A	N/A	233	30 (12.9%)	$106.3M
Total	**225**	**160 (71.1%)**	**960 representing 1,153 potential awards**	**91 representing 113 potential awards (9.48%)**	**$293.6M**

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

Table 2. FY23 PRMRP Application Data by Topic Area

Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Arthritis	36	0 (0.0%)	-
Celiac Disease	7	2 (28.6%)	$6,675,794
Dystonia	10	1 (10.0%)	$2,500,524
Eating Disorders	8	0 (0.0%)	-
Eczema	9	1 (11.1%)	$3,184,920
Ehlers-Danlos Syndrome	4	0 (0.0%)	-
Endometriosis	16	1 (6.2%)	$2,497,264
Epidermolysis Bullosa	4	1 (25.0%)	$4,288,290
Familial Hypercholesterolemia	3	0 (0.0%)	-
Fibrous Dysplasia/ McCune-Albright Syndrome	1	0 (0.0%)	-
Focal Segmental Glomerulosclerosis	14	6 (42.9%)	$17,465,584
Food Allergies	5	0 (0.0%)	-
Fragile X	9	0 (0.0%)	-
Frontotemporal Degeneration	11	2 (18.2%)	$5,590,571
Guillain-Barré Syndrome	2	0 (0.0%)	-
Hemorrhage Control	54	6 (11.1%)	$21,447,298
Hepatitis B	12	2 (16.7%)	$2,964,023
Hereditary Ataxia	10	3 (30.0%)	$9,241,805

Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Hydrocephalus	6	2 (33.3%)	$11,195,586
Hypercholesterolemia	18	0 (0.0%)	-
Inflammatory Bowel Disease	44	2 (4.5%)	$5,603,732
Interstitial Cystitis	2	0 (0.0%)	-
Lymphatic Disease	6	2 (33.3%)	$6,023,925
Lymphedema	5	0 (0.0%)	-
Malaria	27	2 (7.4%)	$4,772,680
Maternal Mental Health	10	2 (20.0%)	$9,695,374
Mitochondrial Disease	16	3 (18.8%)	$9,996,013
Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome	7	0 (0.0%)	-
Myotonic Dystrophy	8	2 (25.0%)	$5,939,066
Nephrotic Syndrome	7	1 (14.3%)	$2,761,717
Neuroactive Steroids	3	0 (0.0%)	-
Neuroinflammatory Responses to Emerging Viral Diseases	24	2 (8.3%)	$932,245
Non-Opioid Therapy for Pain Management	39	2 (5.1%)	$6,390,431
Orthopaedics	48	2 (4.2%)	$3,162,918
Pancreatitis	16	3 (18.8%)	$7,071,990
Peripheral Neuropathy	18	1 (5.6%)	$3,229,783
Polycystic Kidney Disease	20	1 (5.0%)	$2,631,514
Pressure Ulcers	16	0 (0.0%)	-
Proteomics	34	3 (8.8%)	$8,167,068
Pulmonary Fibrosis	24	2 (6.3%)	$12,881,312
Respiratory Health	85	7 (8.2%)	$35,266,023
Rheumatoid Arthritis	14	2 (14.3%)	$4,668,136
Scleroderma	14	2 (14.3%)	$4,058,033
Sickle-Cell Disease	9	2 (22.2%)	$7,370,807
Sleep Disorders and Restriction	19	3 (15.8%)	$10,521,600
Suicide Prevention	23	3 (13.0%)	$7,612,372
Trauma	141	13 (9.2%)	$37,541,420
Tuberculosis	27	2 (7.4%)	$10,268,931
Vascular Malformations	15	0 (0.0%)	-
Von Hippel-Lindau Syndrome Benign Manifestations	0	-	-
Totals	**960**	**91 (9.5%)**	**$293,618,749**

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

FY23 PRMRP CTA applications were peer reviewed via videoconference in September 2023 by nine panels comprised of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PA.

FY23 PRMRP FPA applications were peer reviewed via videoconference in September 2023 by 15 panels comprised of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PA.

FY23 PRMRP IIRA and TTDA applications were peer reviewed via videoconference in August 2023 by 64 panels comprised of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

FY23 PRMRP LBIRA applications were peer reviewed via videoconference in July 2023 by five panels comprised of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PA.

Each peer review panel included a Chair, an average of seven scientific reviewers, an average of two 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 November 2023 by the FY23 Programmatic Panel and ad hoc reviewers comprised of a diverse group of basic and clinical scientists from each branch of the military Services, the Defense Health Agency, the Department of Veterans Affairs, the Department of Health and Human Services, academic institutions, and private industry. 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; adherence to the intent of the award mechanism; relative [clinical] impact; relevance to the FY23 PRMRP Topic Areas; relevance to the FY23 PRMRP Strategic Goals; relevance to military health; and program portfolio composition. After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.