US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2022 (FY22) PEER REVIEWED MEDICAL RESEARCH PROGRAM (PRMRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY22 PRMRP called for applications in response to program announcements (PAs) for five award mechanisms released in March 2022:

- Clinical Trial Award (CTA)
- Expansion Award (EA)
- Focused Program Award (FPA)
- Investigator-Initiated Research Award (IIRA)
- Technology/Therapeutic Development Award (TTDA)

Pre-applications were received for the CTA, EA, and FPA PAs in May 2022 and screened in May–June 2022 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 the CTA, EA, and FPA PAs in August 2022 and peer reviewed in September–October 2022. Programmatic review was conducted in November–December 2022.

In response to the CTA PA, 131 pre-applications were received and the Principal Investigators (PIs) of 97 of these were invited to submit a full application. Eighty-three (83) compliant applications were received and 8 (9.6%) were recommended for funding for a total of $39.1 million (M).

In response to the EA PA, 118 pre-applications were received and the PIs of 90 of these were invited to submit a full application. Seventy-eight (78) compliant applications were received and 10 (12.8%) were recommended for funding for a total of $43.5M.

In response to the FPA PA, 60 pre-applications were received and the PIs of 41 of these were invited to submit a full application. Twenty-eight (28) compliant applications were received and 5 (17.9%) were recommended for funding for a total of $39.9M.

Applications were received for the IIRA and TTDA PAs in May 2022 and peer reviewed in August 2022. Programmatic review was conducted in November–December 2022.

In response to the IIRA PA, 427 compliant applications representing 580 potential awards were received and 32 (representing 48 awards, 7.5%) were recommended for funding for a total of $84.8M.

In response to the TTDA PA, 183 compliant applications were received and 24 (13.1%) were recommended for funding for a total of $96.5M.

Submission and award data for the FY22 PRMRP are summarized in the tables below.

Table 1. Submission/Award Data for the FY22 PRMRP[*]

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Clinical Trial Award	131	97 (74.0%)	83	8 (9.6%)	$39.1M
Expansion Award	118	90 (76.3%)	78	10 (12.8%)	$43.5M
Focused Program Award	60	41 (68.3%)	28	5 (17.9%)	$39.9M
Investigator-Initiated Research Award[‡]	N/A	N/A	427	32 (7.5%)	$84.8M
Technology/ Therapeutic Development Award	N/A	N/A	183	24 (13.1%)	$96.5M
Total[§]	**309**	**228 (73.8%)**	**799**	**79 (9.9%)**	**$303.8M**

[*]These data reflect funding recommendations only. Pending FY22 award negotiations, final numbers will be available after September 30, 2022.

[‡]427 applications received representing 580 potential awards; 32 applications recommended for funding representing 48 awards.

§799 applications received representing 952 potential awards; 79 applications recommended for funding representing 95 awards.

Table 2. FY22 PRMRP Application Data by Topic Area

Topic Area	Compliant Applications	Applications Recommended for Funding (%)	Recommended Budget
Arthritis	42	3 (7.1%)	$6,040,952
Cardiomyopathy	36	5 (13.9%)	$22,918,737
Congenital Heart Disease	14	1 (7.1%)	$2,440,177
Diabetes	34	2 (5.9%)	$6,147,588
Dystonia	9	1 (11.1%)	$4,175,247
Eating Disorders	9	2 (22.2%)	$7,395,522
Ehlers-Danlos Syndrome	3	0 (0.0%)	-
Endometriosis	7	1 (14.3%)	$2,558,923
Epidermolysis Bullosa	9	3 (33.3%)	$9,224,603
Familial Hypercholesterolemia	1	0 (0.0%)	-
Fibrous Dysplasia	3	1 (33.3%)	$3,346,788
Focal Segmental Glomerulosclerosis	7	3 (42.9%)	$10,949,519

Topic Area	Compliant Applications	Applications Recommended for Funding (%)	Recommended Budget
Food Allergies	5	0 (0.0%)	-
Fragile X	3	0 (0.0%)	-
Friedreich's Ataxia	12	3 (25.0%)	$13,174,635
Frontotemporal Degeneration	9	1 (11.1%)	$7,367,755
Guillain-Barré Syndrome	1	0 (0.0%)	-
Hemorrhage Control	25	0 (0.0%)	-
Hepatitis B	8	0 (0.0%)	-
Hydrocephalus	9	4 (44.4%)	$18,890,739
Hypercholesterolemia	5	0 (0.0%)	-
Hypertension	21	1 (4.8%)	$3,989,240
Inflammatory Bowel Disease	26	2 (7.7%)	$7,537,375
Interstitial Cystitis	1	0 (0.0%)	-
Malaria	15	2 (13.3%)	$4,986,516
Mitochondrial Disease	6	0 (0.0%)	-
Musculoskeletal Disorders (related to acute and chronic bone conditions and injuries)	37	3 (8.1%)	$14,288,092
Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome	4	0 (0.0%)	-
Myotonic Dystrophy	4	2 (50.0%)	$8,846,000
Nephrotic Syndrome	1	0 (0.0%)	-
Non-Opioid Therapy for Pain Management	27	3 (11.1%)	$13,571,560
Nutrition Optimization	10	1 (10.0%)	$3,054,361
Pancreatitis	12	4 (33.3%)	$14,767,846
Pathogen-Inactivated Blood Products	1	0 (0.0%)	-
Peripheral Neuropathy	17	1 (5.9%)	$4,000,000
Plant-Based Vaccines	6	2 (33.3%)	$18,046,410
Platelet-Like Cell Production	1	0 (0.0%)	-
Polycystic Kidney Disease	11	2 (18.2%)	$11,182,076
Pressure Ulcers	15	3 (20.0%)	$9,041,117
Pulmonary Fibrosis	21	1 (4.8%)	$4,399,164
Respiratory Health	55	3 (5.5%)	$13,180,257
Rett Syndrome	6	0 (0.0%)	-
Rheumatoid Arthritis	14	0 (0.0%)	-
Sleep Disorders and Restriction	12	3 (25.0%)	$7,026,558
Suicide Prevention	12	2 (16.7%)	$5,855,132
Sustained Release Drug Delivery	25	2 (8.0%)	$4,505,789
Trauma	70	7 (10.0%)	$21,724,858
Vascular Malformations	13	2 (15.4%)	$6,685,859
Viral Diseases	93	2 (2.2%)	$10,663,234
Women's Heart Disease	12	1 (8.3%)	$1,803,335
Totals	**799**	**79 (9.9%)**	**$303,785,964**

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

CTA, EA, FPA, IIRA, and TTDA applications were peer reviewed in August–October 2022 by panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs. Each peer review panel included a Chair, scientific reviewers, consumer reviewers, and a nonvoting Scientific Review Officer. CTA and EA applications were reviewed by 21 panels. FPA applications were reviewed by 13 panels. IIRA and TTDA applications were reviewed by 53 panels. 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 2022 by the FY22 Programmatic Panel that was comprised of representatives of each branch of the military Services, USAMRDC headquarters, the Department of Veterans Affairs, the Defense Health Agency, the Department of Health and Human Services, academia, and consumer advocates, each contributing special expertise or interest in the FY22 PRMRP Topic Areas. 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; relative [clinical] impact; relevance to the FY22 PRMRP Topic Areas; relevance to the FY22 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.