US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2021 (FY21) PEER REVIEWED MEDICAL RESEARCH PROGRAM (PRMRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY21 PRMRP called for applications in response to program announcements (PAs) for five award mechanisms released in March 2021:

- 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 these five PAs in April and May 2021 and screened in May and June 2021 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 five PAs in August and September 2021 and peer reviewed in October 2021. Programmatic review was conducted in December 2021.

Submission and award data for the FY21 PRMRP are summarized in the tables below. Application counts represent numbers of individual projects; the recommended budgets include the budgets of EA and IIRA Partnering PI applications that were recommended for funding.

Table 1. FY21 PRMRP Programmatic Review II Submission/Award Data*

Mechanism	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
CTA	81	10‡ (12.3%)	$22,508,683
EA	83	17 (20.5%)	$42,389,349
FPA	32	5 (15.6%)	$50,635,707
IIRA	300	48 (16.0%)	$127,019,245
TTDA	113	18 (15.9%)	$61,763,461
Total§	**609**	**98 (16.1%)**	**$304,316,445**

*These data reflect funding recommendations only. Pending FY21 award negotiations, final numbers will be available after September 30, 2022.

‡Seven CTAs were with Planning Phase and three were Clinical Trial only.

§A total 24 EA applications and 136 IIRA applications included the Partnering Principal Investigator Option (PPIO), representing an additional 160 potential awards; of these, 7 EA and 22 IIRA applications with the PPIO were recommended for funding, representing an additional 29 awards.

Table 2. FY21 PRMRP Application Data by Primary Topic Area

Primary Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Arthritis	41	2 (4.9%)	$7,475,367
Burn Pit Exposure	8	2 (25.0%)	$6,002,465
Cardiomyopathy	32	3 (9.4%)	$10,892,709
Congenital Heart Disease	24	3 (12.5%)	$17,349,909
Diabetes	48	2 (4.2%)	$4,289,841
Dystonia	10	3 (30.0%)	$4,808,519
Eating Disorders	8	0 (0%)	-
Emerging Viral Diseases	55	7 (12.7%)	$13,002,749
Endometriosis	5	0 (0%)	-
Epidermolysis Bullosa	5	1 (20.0%)	$11,354,522
Familial Hypercholesterolemia	1	0 (0%)	-
Fibrous Dysplasia	1	0 (0%)	-
Focal Segmental Glomerulosclerosis	7	5 (71.4%)	$11,165,723
Food Allergies	4	0 (0%)	-
Fragile X	6	1 (16.7%)	$3,048,711
Frontotemporal Degeneration	10	2 (20.0%)	$5,645,021
Hemorrhage Control	29	6 (20.7%)	$12,484,246
Hepatitis B	4	2 (50.0%)	$8,675,924
Hydrocephalus	7	2 (28.6%)	$5,289,361
Hypertension	8	2 (25.0%)	$5,776,862
Inflammatory Bowel Diseases	20	3 (15.0%)	$10,724,597
Malaria	25	7 (28.0%)	$21,630,882
Metals Toxicology	7	0 (0%)	-
Mitochondrial Disease	13	5 (38.5%)	$23,997,543
Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome	4	1 (25.0%)	$2,517,199
Myotonic Dystrophy	2	0 (0%)	-
Non-Opioid Therapy for Pain Management	36	6 (16.7%)	$22,004,621
Nutrition Optimization	11	3 (27.3%)	$12,847,075
Pathogen-Inactivated Blood Products	0	0 (0%)	-
Peripheral Neuropathy	25	3 (12.0%)	$6,871,401
Plant-Based Vaccines	1	0 (0%)	-
Platelet-Like Cell Production	1	0 (0%)	-
Polycystic Kidney Disease	10	2 (20.0%)	$6,304,948
Pressure Ulcers	9	1 (11.1%)	$1,773,512
Pulmonary Fibrosis	8	2 (25.0%)	$5,698,277
Respiratory Health	46	10 (21.7%)	$29,043,473
Rheumatoid Arthritis	8	1 (12.5%)	$1,836,197
Sleep Disorders and Restriction	21	2 (9.5%)	$6,512,790
Suicide Prevention	10	2 (20.0%)	$8,914,068
Sustained Release Drug Delivery	23	4 (17.4%)	$9,422,300

Primary Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Vascular Malformations	6	1 (16.7%)	$2,584,000
Women's Heart Disease	10	2 (20.0%)	$4,371,633
Totals	**609**	**98 (16.1%)**	**$304,316,445**

Table 3. FY21 PRMRP Application Data by Secondary Topic Area

Secondary Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Arthritis	4	1 (25.0%)	$2,077,406
Burn Pit Exposure	7	0 (0%)	-
Cardiomyopathy	9	2 (22.2%)	$6,445,195
Congenital Heart Disease	6	0 (0%)	-
Diabetes	15	3 (20.0%)	$14,746,726
Dystonia	0	-	-
Eating Disorders	1	0 (0%)	-
Emerging Viral Diseases	12	3 (25.0%)	$18,991,441
Endometriosis	0	-	-
Epidermolysis Bullosa	0	-	-
Familial Hypercholesterolemia	0	-	-
Fibrous Dysplasia	0	-	-
Focal Segmental Glomerulosclerosis	0	-	-
Food Allergies	0	-	-
Fragile X	0	-	-
Frontotemporal Degeneration	2	0 (0%)	-
Hemorrhage Control	1	0 (0%)	-
Hepatitis B	0	-	-
Hydrocephalus	1	0 (0%)	-
Hypertension	5	2 (40.0%)	$5,254,145
Inflammatory Bowel Diseases	1	0 (0%)	-
Malaria	1	0 (0%)	-
Metals Toxicology	1	0 (0%)	-
Mitochondrial Disease	4	0 (0%)	-
Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome	0	-	-
Myotonic Dystrophy	1	0 (0%)	-
Non-Opioid Therapy for Pain Management	10	0 (0%)	-
Nutrition Optimization	6	0 (0%)	-
Pathogen-Inactivated Blood Products	1	0 (0%)	-
Peripheral Neuropathy	10	1 (10.0%)	$2,528,000
Plant-Based Vaccines	2	1 (50.0%)	$2,383,881

Secondary Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Platelet-Like Cell Production	4	0 (0%)	-
Polycystic Kidney Disease	0	-	-
Pressure Ulcers	3	0 (0%)	-
Pulmonary Fibrosis	6	0 (0%)	-
Respiratory Health	28	5 (17.9%)	$11,647,495
Rheumatoid Arthritis	0	-	-
Sleep Disorders and Restriction	4	0 (0%)	-
Suicide Prevention	6	1 (16.7%)	$608,435
Sustained Release Drug Delivery	21	3 (14.3%)	$7,842,686
Vascular Malformations	2	0 (0%)	-
Women's Heart Disease	8	2 (25.0%)	$8,204,709
(None)	453	74 (16.3%)	$223,586,326
Totals	**609**	**98 (16.1%)**	**$304,316,445**

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

Peer review for applications received in response to these five PAs was conducted in October 2021 by review panels based on the evaluation criteria specified in each respective PA. Each peer review panel included a Chair, scientific reviewers, consumer reviewers, and a nonvoting Scientific Review Officer. The EA, IIRA, and TTDA applications were peer reviewed by 38 panels. The CTA applications were peer reviewed by 19 panels. The FPA applications were peer reviewed by 17 panels.

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 December 2021 by the FY21 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, the Office of the Principal Assistant for Acquisition, academia, and consumer advocates. 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; program portfolio composition; relevance to military health; and relative impact. After programmatic review, the Commanding General, USAMRDC, approved funding for the applications recommended during programmatic review.