US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2018 (FY18) PEER REVIEWED MEDICAL RESEARCH PROGRAM (PRMRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY18 PRMRP called for applications in response to program announcements (PAs) for five award mechanisms released in April and May 2018:

- Clinical Trial Award
- Expansion Award
- Focused Program Award
- Investigator-Initiated Research Award
- Technology/Therapeutic Development Award

Pre-applications were received for these five PAs in June 2018 and screened in July 2018 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 September 2018 and peer reviewed in October and November 2018. Programmatic review was conducted in January 2019.

In response to the Clinical Trial Award PA, 167 pre-applications were received and the PIs of 89 of these were invited to submit a full application. Seventy-two (72) compliant applications were received and 6 (8.3%) were recommended for funding for a total of $21.1 million (M).

In response to the Expansion Award PA, 96 pre-applications were received and the Principal Investigators (PIs) of 65 of these were invited to submit a full application. Sixty (60) compliant applications were received and 10 (16.7%) were recommended for funding for a total of $28.4M.

In response to the Focused Program Award PA, 112 pre-applications were received and the PIs of 40 of these were invited to submit a full application. Thirty-eight (38) compliant applications were received and 2 (5.3%) were recommended for funding for a total of $20.0M.

In response to the Investigator-Initiated Research Award PA, 926 pre-applications were received and the PIs of 425 of these were invited to submit a full application. The Investigator-Initiated Research Award mechanism included a Partnering PI Option, for which two applications were submitted by partnered PIs for conduct of a single research project. Two hundred twenty-six (226) compliant Investigator-Initiated Research Award applications with a single PI were received and 31 (13.7%) were recommended for funding for a total of $54.3M. Three hundred eight (308) compliant Investigator-Initiated Research Award with Partnering PI Option applications were received, representing 154 projects, and 64 (32 projects, 20.8%) were recommended for funding for a total of $69.8M.

In response to the Technology/Therapeutic Development Award PA, 306 pre-applications were received and the PIs of 158 of these were invited to submit a full application. One hundred forty (140) compliant applications were received and 25 (17.9%) were recommended for funding for a total of $87.5M.

These data reflect funding recommendations only. Pending FY18 award negotiations, final numbers will be available after September 30, 2019.

Submission and award data by primary topic area (Table 1) and secondary topic area (Table 2) for the FY18 PRMRP are summarized in the tables below. Application counts represent numbers of individual projects, but the recommended budgets include the budgets of Investigator-Initiated Research Award Partnering PI applications that were recommended for funding.

Table 1. FY18 PRMRP Application Data by Primary Topic Area

Primary Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Acute Lung Injury	39	4 (10.3%)	$15,681,909
Antimicrobial Resistance	51	5 (9.8%)	$18,850,701
Arthritis	8	0 (0.0%)	$0
Burn Pit Exposure	3	1 (33.3%)	$1,472,838
Cardiomyopathy	28	4 (14.3%)	$6,915,702
Cerebellar Ataxia	3	1 (33.3%)	$835,681
Chronic Migraine and Post-Traumatic Headache	8	1 (12.5%)	$9,999,950
Chronic Pain Management	20	3 (15.0%)	$5,123,500
Congenital Heart Disease	17	5 (29.4%)	$15,579,048
Constrictive Bronchiolitis	2	0 (0.0%)	$0
Diabetes	55	6 (10.9%)	$17,995,688
Dystonia	3	2 (66.7%)	$6,839,512
Eating Disorders	5	4 (80.0%)	$8,391,196
Emerging Infectious Diseases	27	2 (7.4%)	$12,870,016
Endometriosis	12	4 (33.3%)	$8,213,323
Epidermolysis Bullosa	5	1 (20.0%)	$2,991,032
Focal Segmental Glomerulosclerosis	8	4 (50.0%)	$10,552,242
Fragile X	11	1 (9.1%)	$1,827,113
Frontotemporal Degeneration	4	1 (25.0%)	$2,265,505
Guillain-Barré Syndrome	2	0 (0.0%)	$0
Hepatitis B and C	15	2 (13.3%)	$4,975,426
Hereditary Angioedema	0	*Not applicable*	*Not applicable*
Hydrocephalus	4	0 (0.0%)	$0

Primary Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Immunomonitoring of Intestinal Transplants	4	1 (25.0%)	$2,317,146
Inflammatory Bowel Diseases	20	2 (10.0%)	$3,250,473
Interstitial Cystitis	1	1 (100.0%)	$3,860,821
Lung Injury	4	1 (25.0%)	$1,820,741
Malaria	25	4 (16.0%)	$10,785,069
Metals Toxicology	5	0 (0.0%)	$0
Mitochondrial Disease	5	1 (20.0%)	$3,566,096
Musculoskeletal Disorders	29	2 (6.9%)	$4,120,291
Myotonic Dystrophy	5	1 (20.0%)	$2,709,375
Non-Opioid Pain Management	12	1 (8.3%)	$4,572,175
Nutrition Optimization	8	0 (0.0%)	$0
Pancreatitis	11	3 (27.3%)	$7,818,793
Pathogen-Inactivated Blood Products	3	1 (33.3%)	$2,414,507
Post-Traumatic Osteoarthritis	21	4 (19.0%)	$11,328,495
Pressure Ulcers	6	0 (0.0%)	$0
Pulmonary Fibrosis	16	2 (12.5%)	$5,240,482
Respiratory Health	14	5 (35.7%)	$9,348,607
Rett Syndrome	6	1 (16.7%)	$4,270,855
Rheumatoid Arthritis	5	0 (0.0%)	$0
Scleroderma	5	0 (0.0%)	$0
Sleep Disorders	12	0 (0.0%)	$0
Spinal Muscular Atrophy	3	0 (0.0%)	$0
Sustained-Release Drug Delivery	10	1 (10.0%)	$4,631,988
Tinnitus	5	2 (40.0%)	$2,498,281
Tissue Regeneration	49	2 (4.1%)	$4,385,060
Tuberculosis	20	2 (10.0%)	$6,045,710
Vaccine Development for Infectious Diseases	39	16 (41.0%)	$30,654,190
Vascular Malformations	8	2 (25.0%)	$4,189,726
Women's Heart Disease	9	0 (0.0%)	$0
Total	**690**	**106 (15.4%)**	**$281,209,263**

Table 2. FY18 PRMRP Application Data by Secondary Topic Area

Secondary Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Acute Lung Injury	2	0 (0.0%)	$0
Antimicrobial Resistance	22	2 (9.1%)	$3,966,673
Arthritis	13	2 (15.4%)	$6,446,612
Burn Pit Exposure	5	0 (0.0%)	$0
Cardiomyopathy	11	2 (18.2%)	$10,010,342
Cerebellar Ataxia	1	0 (0.0%)	$0
Chronic Migraine and Post-Traumatic Headache	1	0 (0.0%)	$0
Chronic Pain Management	17	4 (23.5%)	$18,734,172
Congenital Heart Disease	6	0 (0.0%)	$0
Constrictive Bronchiolitis	4	1 (25.0%)	$1,920,549
Diabetes	11	3 (27.3%)	$5,945,176
Dystonia	2	0 (0.0%)	$0
Eating Disorders	2	0 (0.0%)	$0
Emerging Infectious Diseases	34	10 (29.4%)	$25,353,545
Focal Segmental Glomerulosclerosis	1	1 (100.0%)	$1,329,124
Fragile X	1	0 (0.0%)	$0
Frontotemporal Degeneration	2	1 (50.0%)	$2,709,375
Guillain-Barré Syndrome	2	0 (0.0%)	$0
Hepatitis B and C	1	0 (0.0%)	$0
Hereditary Angioedema	1	0 (0.0%)	$0
Inflammatory Bowel Diseases	4	0 (0.0%)	$0
Lung Injury	23	3 (13.0%)	$5,802,681
Malaria	3	0 (0.0%)	$0
Mitochondrial Disease	6	0 (0.0%)	$0
Musculoskeletal Disorders	28	1 (3.6%)	$1,948,176
Non-Opioid Pain Management	19	1 (5.3%)	$1,956,633
Nutrition Optimization	8	0 (0.0%)	$0
Pathogen-Inactivated Blood Products	4	0 (0.0%)	$0
Post-Traumatic Osteoarthritis	4	0 (0.0%)	$0
Pressure Ulcers	2	0 (0.0%)	$0
Pulmonary Fibrosis	8	1 (12.5%)	$4,911,476
Respiratory Health	18	5 (27.8%)	$12,627,019
Rheumatoid Arthritis	2	0 (0.0%)	$0
Scleroderma	3	0 (0.0%)	$0
Sleep Disorders	2	0 (0.0%)	$0

Secondary Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Sustained-Release Drug Delivery	8	2 (25.0%)	$6,301,323
Tinnitus	1	0 (0.0%)	$0
Tissue Regeneration	27	3 (11.1%)	$6,333,918
Tuberculosis	1	0 (0.0%)	$0
Vaccine Development for Infectious Diseases	19	1 (5.3%)	$1,491,280
Vascular Malformations	2	0 (0.0%)	$0
Women's Heart Disease	6	1 (16.7%)	$3,566,096
No Secondary Topic Area Selected	353	62 (17.6%)	$159,855,093
Total	**690**	**106 (15.4%)**	**$281,209,263**

THE TWO-TIER REVIEW SYSTEM

The USAMRMC developed a review model based on recommendations of the 1993 Institute of Medicine (IOM) 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 and November 2018 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. Expansion Award, Investigator-Initiated Research Award, and Technology/Therapeutic Development Award applications were peer reviewed by 34 panels. The Clinical Trial Award applications were peer reviewed by 19 panels. The Focused Program Award applications were peer reviewed by 20 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 applicants' abstracts, impact and military relevance statements, 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 USAMRMC 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 2019, by the FY18 Programmatic Panel that was comprised of representatives of each branch of the military Services, the Department of Veterans Affairs, the Office of the Assistant Secretary of Defense for Health Affairs, the Department of Health and Human Services, and ad hoc reviewers. 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; programmatic relevance; adherence to the intent of the award mechanism; military relevance; program portfolio composition; and relative impact. After programmatic review, the Commanding General, USAMRMC, and the Director of the Defense Health Agency J9, Research and Development Directorate approved funding for the applications recommended during programmatic review.