US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2017 (FY17) PEER REVIEWED MEDICAL RESEARCH PROGRAM (PRMRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY17 PRMRP called for applications in response to the Discovery Award Program Announcement (PA) released in May 2017.

In response to the Discovery Award PA, 480 compliant applications were received in August 2017 and peer reviewed in September 2017. Programmatic review was conducted in November 2017.

Submission and award data for the FY17 Discovery Award are summarized in the tables below.

Table 1. Submission/Award Data for the FY17 PRMRP*

| Mechanism | Compliant Applications Received | Applications Recommended for Funding (%) | Total Funds |
|-----------------|------------------------------------|--|----------------|
| Discovery Award | 480 | 69 (14%) | \$20,433,677 |

^{*}These data reflect funding recommendations only. Pending FY17 award negotiations, final numbers will be available after September 30, 2018.

Table 2. FY17 PRMRP Application Data by Topic Area

| Topic Area | Compliant Applications Received | Applications Recommended for Funding (%) | Total Funds |
|--|---------------------------------|--|-------------|
| Acute Lung Injury | 17 | 2 (12%) | \$550,344 |
| Antimicrobial Resistance | 57 | 7 (12%) | \$1,980,300 |
| Arthritis | 7 | 1 (14%) | \$327,500 |
| Burn Pit Exposure | 1 | 0 (0%) | \$0 |
| Chronic Migraine and Post- Traumatic Headache | 3 | 0 (0%) | \$0 |
| Congenital Heart Disease | 15 | 3 (20%) | \$954,507 |
| Constrictive Bronchiolitis | 1 | 0 (0%) | \$0 |
| Diabetes | 48 | 7 (15%) | \$2,160,285 |
| Diarrheal Diseases | 12 | 4 (33%) | \$1,126,758 |
| Dystonia | 13 | 2 (15%) | \$591,868 |
| Early Trauma Thermal Regulation | 1 | 0 (0%) | \$0 |
| Eating Disorders | 6 | 0 (0%) | \$0 |

| Topic Area | Compliant Applications Received | Applications Recommended for Funding (%) | Total Funds |
|---|---------------------------------|--|--------------|
| Emerging Infectious Diseases | 32 | 7 (22%) | \$2,070,613 |
| Epidermolysis Bullosa | 3 | 0 (0%) | \$0 |
| Focal Segmental Glomerulosclerosis | 3 | 0 (0%) | \$0 |
| Fragile X Syndrome | 5 | 0 (0%) | \$0 |
| Guillain-Barré Syndrome | 1 | 0 (0%) | \$0 |
| Hepatitis B and C | 2 | 1 (50%) | \$324,000 |
| Hereditary Angioedema | 0 | 0 (0%) | \$0 |
| Hydrocephalus | 6 | 0 (0%) | \$0 |
| Immunomonitoring of Intestinal Transplants | 1 | 0 (0%) | \$0 |
| Inflammatory Bowel Diseases | 17 | 1 (6%) | \$325,000 |
| Influenza | 12 | 3 (25%) | \$753,757 |
| Integrative Medicine | 5 | 0 (0%) | \$0 |
| Interstitial Cystitis | 2 | 1 (50%) | \$262,233 |
| Malaria | 14 | 2 (14%) | \$643,985 |
| Metals Toxicology | 11 | 1 (9%) | \$304,668 |
| Mitochondrial Disease | 9 | 3 (33%) | \$965,998 |
| Musculoskeletal Disorders | 13 | 2 (15%) | \$560,870 |
| Nanomaterials for Bone Regeneration | 15 | 2 (13%) | \$611,858 |
| Non-Opioid Pain Management | 7 | 0 (0%) | \$0 |
| Pancreatitis | 8 | 2 (25%) | \$639,338 |
| Pathogen-Inactivated Dried Cryoprecipitate | 0 | 0 (0%) | \$0 |
| Polycystic Kidney Disease | 5 | 0 (0%) | \$0 |
| Post-Traumatic Osteoarthritis | 19 | 3 (16%) | \$940,675 |
| Pulmonary Fibrosis | 11 | 2 (18%) | \$594,447 |
| Respiratory Health | 13 | 2 (15%) | \$515,843 |
| Rett Syndrome | 4 | 0 (0%) | \$0 |
| Rheumatoid Arthritis | 9 | 0 (0%) | \$0 |
| Scleroderma | 3 | 0 (0%) | \$0 |
| Sleep Disorders | 12 | 0 (0%) | \$0 |
| Spinal Muscular Atrophy | 4 | 1 (25%) | \$318,640 |
| Sustained-Release Drug Delivery | 10 | 1 (10%) | \$263,939 |
| Tinnitus | 3 | 0 (0%) | \$0 |
| Tuberculosis | 9 | 3 (33%) | \$845,584 |
| Vaccine Development for Infectious Disease | 17 | 3 (18%) | \$976,735 |
| Vascular Malformations | 7 | 1 (14%) | \$309,000 |
| Women's Heart Disease | 7 | 2 (29%) | \$514,932 |
| Total | 480 | 69 | \$20,433,677 |

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

Discovery Award applications were peer reviewed in September 2017 by 34 panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PA. Reviewers were blinded to the identity of the Principal Investigator (PI), collaborators, and their organizations.

Online Review Panels

The Discovery Award scientific peer review panel was conducted online, with each application reviewed by two scientists and one consumer. Moderated online discussions took place following individual reviewer score input if there was a discrepancy in scoring range of more than two adjectival scores [e.g., Outstanding score (1.0-1.5) and Fair (2.6-3.5)].

Application Scoring

Evaluation Criteria Scores: Panel members were asked to rate each peer review evaluation criterion as published in the 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 innovation 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 November 2017 by the FY17 Programmatic Panel, 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 Discovery Award PA were as follows: ratings and evaluations of the scientific peer review panels; adherence to the intent of the award mechanism; program portfolio composition; military relevance; and relative impact and innovation. Programmatic reviewers were blinded to the identity of the PI, collaborators, and their organizations. After programmatic review, the Commanding General, USAMRMC, and the Director of the Defense Health Agency, Research, Development and Acquisition Directorate approved funding for the applications recommended during programmatic review.