US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2016 (FY16) BREAST CANCER RESEARCH PROGRAM (BCRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY16 BCRP called for applications in response to program announcements (PAs) for two award mechanisms released in March 2016:

- Distinguished Investigator Award
- Innovator Award

Pre-applications were received for these Distinguished Investigator Award and Innovator Award PAs in April 2016 and screened in June 2016 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 August 2016 and peer reviewed in October 2016. Programmatic review was conducted in November 2016.

In response to the Distinguished Investigator PA, 9 pre-applications were received. The Principal Investigators (PIs) of two pre-applications were invited to submit a full application. Two compliant applications were received, peer reviewed, and underwent Stage 1 programmatic review. No applications were invited to Stage 2 programmatic review.

In response to the Innovator PA, 23 pre-applications were received. The PIs of three pre-applications were invited to submit a full application. Three compliant applications were received, peer reviewed, and underwent Stage 1 programmatic review. No applications were invited to Stage 2 programmatic review.

Submission and award data for the FY16 BCRP are summarized in the table(s) below.

Table 1. Submission/Award Data for the FY16 BCRP Recommendations from Stage 1 Programmatic Review

| Mechanism | Pre- Applications Received | Pre- Applications Invited (%) | Compliant Applications Received | Applications Recommended for Stage 2 Programmatic Review (%) |
|-------------------------------|----------------------------------|-------------------------------------|---------------------------------------|--|
| Distinguished Investigator | 9 | 2 (22 %) | 2 | 0 (0%) |
| Innovator | 23 | 3 (13%) | 3 | 0 (0%) |
| Total | 32 | 5 (16%) | 5 | 0 (0%) |

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

Distinguished Investigator Award and Innovator Award applications were peer reviewed in October 2016 by two 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, a consumer reviewer, and a nonvoting Scientific Review Officer (SRO). 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

In contrast to the typical technical merit review process, no numerical scores were assigned to the Innovator Award and Distinguished Investigator Award applications. Instead, reviewers were asked to address specific questions pertaining to the applicant's qualifications, accomplishments, research goals or ideas, and leadership skills. Each reviewer provided a final adjectival level of enthusiasm (high, medium, low) for the application.

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 levels of enthusiasm, 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

Stage 1 programmatic review was conducted in November 2016, by the FY16 Programmatic Panel, comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in breast cancer. 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 as published for the Innovator and Distinguished Investigator Awards were as follows: Stage 1 – Ratings and evaluations of the scientific peer reviewers; relative innovation; and adherence to the intent of the award mechanism; Stage 2 – Understanding of barriers in breast cancer; articulation of a realistic vision with a high potential for impact in breast cancer; and leadership capabilities to form partnerships and collaborations that will impact breast cancer.