US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2023 (FY23) BREAST CANCER RESEARCH PROGRAM (BCRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY23 BCRP called for applications in response to a program announcement (PA) for the following award mechanism released in May 2023:

• Innovator Award

Pre-applications were received for the Innovator Award PA in June 2023 and screened in July 2023 to determine which investigators would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the PA.

Applications were received in September 2023 and peer reviewed in November 2023. Programmatic review (*Stage 1*) was conducted in January 2024.

In response to the Innovator Award PA, five pre-applications were received and the Principal Investigators (PIs) of three of these were invited to submit a full application. Two compliant applications were received, and one was recommended for invitation to Stage 2 Programmatic Review (oral presentation). One application (50%) was recommended for funding after Stage 2 Programmatic Review in February 2024 for a total of \$10.2 million (M).

Submission and award data for the FY23 BCRP Innovator Award are summarized in the table below.

Mechanism	Pre- Applications Received	Pre- Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Innovator Award	5	3 (60%)	2	1 (50%)	\$10.2M

*These data reflect funding recommendations only. Pending FY23 award negotiations, final numbers will be available after September 30, 2024.

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

Innovator Award applications were peer reviewed in November 2023 by a single panel of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PA.

The peer review panel included a Chair, seven scientific reviewers, two consumer reviewers, and a nonvoting Scientific Review Officer. The primary responsibility of the panelists was to review the technical merit of each application based upon the evaluation criteria specified in the PA.

Individual Peer Review Panels

The Chair for the 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 criteria scores were assigned to the Innovator 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 then voted confidentially on an overall level of enthusiasm (High, Medium, or Low).

Summary Statements: The Scientific Review Officer on the 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

For the Innovator Award, Stage 1 Programmatic Review was conducted in January 2024 and Stage 2 Programmatic Review was conducted in February 2024 by the FY23 Programmatic Panel. The Programmatic Panel is comprised of a diverse group of scientists, clinicians, 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 published in the Innovator Award PA for Stage 1 were as follows: ratings and evaluations of the peer reviewers; relative innovation; and adherence to the intent of the award mechanism. For Stage 2, the criteria include: understanding the barriers in breast cancer; articulation of a realistic vision with a high potential to impact breast cancer; and leadership capabilities to form partnerships and collaborations that will impact breast cancer.

After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.