

**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 program announcements (PAs) for four award mechanisms released in May 2023 and one award mechanism released in June 2023:

- Breakthrough Award Levels 1 and 2 (released May 2023)
- Breakthrough Award Level 3 (released May 2023)
- Breakthrough Award Level 4 (released May 2023)
- Clinical Research Extension Award (released June 2023)
- Transformative Breast Cancer Consortium Award (released May 2023)

Applications were received for the Breakthrough Award Levels 1 and 2 PA in August 2023 and peer reviewed in October 2023. Programmatic review was conducted in December 2023 and January 2024.

In response to the Breakthrough Award Levels 1 and 2 PA, 292 compliant applications were received and 11 (3.8%) were recommended for funding for a total of \$18.5 million (M).

Applications were received for the Clinical Research Extension Award PA in September 2023 and peer reviewed in November 2023. Programmatic review was conducted in January 2024.

In response to the Clinical Research Extension Award PA, one compliant application was received and was recommended for funding for a total of \$9.7M.

Pre-applications were received for the Breakthrough Award Level 3, Breakthrough Award Level 4, and Transformative Breast Cancer Consortium Award PAs 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 relevant PA.

In response to the Breakthrough Award Level 3 PA, 11 pre-applications were received, and the PIs of 6 of these were invited to submit a full application. No compliant applications were received.

In response to the Breakthrough Award Level 4 PA, one compliant pre-application was received, and none were invited to submit a full application.

Applications were received for the Transformative Breast Cancer Consortium Award PA in September 2023 and peer reviewed in November 2023. Programmatic review (*Stage 1*) was conducted in January 2024.

In response to the Transformative Breast Cancer Consortium Award PA, two pre-applications were received and the PIs of one of these were invited to submit a full application. One compliant application was received, and none were recommended for invitation to Stage 2 programmatic review (oral application).

Submission and award data for the FY23 BCRP are summarized in the tables below.

Table 1. Submission/Award Data for the FY23 BCRP*

Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Breakthrough Award Level 1	163	1 (0.6%)	\$726,750
Breakthrough Award Level 2	129	10 (7.8%)	\$17,751,858
Clinical Research Extension Award	1	1 (100.0%)	\$9,712,213
Totals	293	12 (4.1%)	\$28,190,821

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

Table 2. Submission/Award Data for the FY23 BCRP from Stage 1 Programmatic Review

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Stage 2 Programmatic Review (%)
Transformative Breast Cancer Consortium Award	2	1 (50%)	1	0 (0%)

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

Breakthrough Award Levels 1 and 2 applications were peer reviewed in October 2023 by 16 panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PA.

Clinical Research Extension Award and Transformative Breast Cancer Consortium Award applications were peer reviewed in November 2023 by one panel of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PA.

Each peer review panel included a Chair, an average of six scientific reviewers, an average of 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 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

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 of the Breakthrough Award Levels 1 and 2 was conducted by the FY23 Programmatic Panel and ad hoc reviewers in December 2023 and January 2024. For the Clinical Research Extension Award and Transformative Breast Cancer Consortium Award (Stage 1), programmatic review was conducted in January 2024 by the FY23 Programmatic Panel. The Programmatic Panel and ad hoc reviewers are 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 Breakthrough Award Levels 1 and 2 PA were as follows: ratings and evaluations of the peer reviewers; adherence to the intent of the award mechanism; program portfolio composition; relative impact; and relative innovation (Breakthrough Award Level 1 only).

Programmatic review criteria published in the Clinical Research Extension Award PA were as follows: ratings and evaluations of the peer reviewers; adherence to the intent of the award mechanism; program portfolio composition; and relative impact.

Programmatic review criteria published in the Transformative Breast Cancer Consortium Award PA for Stage 1 were as follows: ratings and evaluations of the peer reviewers; adherence to the intent of the award mechanism; program portfolio composition; relative impact; and relative innovation. For Stage 2, the criteria include: understanding of conceptual or intellectual or scientific barriers in breast cancer and articulation of how the consortium will address them; articulation of how the consortium's team-based approach will challenge existing paradigms or develop new paradigms that will fundamentally and significantly transform and disrupt the present breast cancer landscape; articulation of how the consortium will take a team-based, integrated approach and make a transformative impact in people's lives; and consortium's capability to create an environment that fosters innovation.

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