US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2024 (FY24) BREAST CANCER RESEARCH PROGRAM (BCRP)

DESCRIPTION OF REVIEW PROCEDURES

The FY24 BCRP called for applications in response to program announcements (PAs) for three award mechanisms released in March and June 2024:

- Breakthrough Award Levels 1 and 2 (June 2024)
- Breakthrough Award Level 4 (March 2024)
- Clinical Research Extension Award (June 2024)

The BCRP received pre-applications for the Breakthrough Award Level 4 in May 2024 and screened them in June 2024. The screening followed the pre-application evaluation criteria specified in the PA to determine which principal investigators (PIs) to invite to submit full applications. The BCRP received applications in August 2024, and they underwent peer review in October 2024. The BCRP conducted stage 1 programmatic review in December 2024 and stage 2 (oral presentation) programmatic review in February 2025.

The BCRP received applications for Breakthrough Award Levels 1 and 2 and the Clinical Research Extension Award in September 2024, and they underwent peer review in December 2024. The BCRP conducted programmatic review in February 2025.

In response to the Breakthrough Award Level 4 PA, the BCRP received 10 pre-applications and invited three of these to submit a full application. The BCRP received two compliant applications, recommended one application for invitation to stage 2 (oral presentation) programmatic review, and recommended funding one application (50.0%) for a total of \$21.2M.

In response to the Breakthrough Award Levels 1 and 2 PA, the BCRP received 237 compliant applications and recommended funding 11 applications (4.6%) for a total of \$17.9 million (M).

In response to the Clinical Research Extension Award PA, the BCRP received six compliant applications and recommended funding zero applications (0.0%) for a total of \$0.0M.

Tables 1 and 2 show submission and award data summarized for the FY24 BCRP.

Mechanism	Pre- Applications Received	Pre- Applications Invited (%)	Compliant Applications Received	Applications Recommended for Stage 2 Programmatic Review (%)	Applications Recommended for Funding (%)	Total Funds
Breakthrough Award Level 4	10	3 (33.3%)	2	1	1 (50.0%)	\$21.2M

Table 1. Submission/Award Data for the FY24 BCRP Stage 2 Programmatic Review*

*These data reflect funding recommendations only. Pending FY24 award negotiations, final numbers will be available after September 30, 2025.

Mechanism	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Breakthrough Award Levels 1 and 2	237	11 (4.6%)	\$17.9M
Clinical Research Extension Award	6	0	0
Totals	243	11 (4.5%)	\$17.9M

Table 2. Submission/Award Data for the FY24 BCRP*

^{*}These data reflect funding recommendations only. Pending FY24 award negotiations, final numbers will be available after September 30, 2025.

THE TWO-TIER REVIEW SYSTEM

The USAMRDC developed a review model based on recommendations 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 report recommended a two-tier review process that reflects not only the traditional strengths of existing peer review systems but is also tailored to accommodate program goals. The Command adheres 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

The BCRP conducted peer review for the Breakthrough Award Levels 1 and 2, Breakthrough Award Level 4, and Clinical Research Extension Award applications in October and December 2024, utilizing 15 panels of researchers, clinicians and consumer advocates. The panel members based their evaluations on criteria specified in the PAs.

Each peer review panel included a Chair, an average of 8 scientific reviewers, an average of 2 consumer reviewers, and a nonvoting Scientific Review Officer. The panelists' primary responsibility 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. The panels discussed each individual application. The Chair called on 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 the panel members then rated the applications confidentially.

Application Scoring

Evaluation Criteria Scores: Panel members rated each application based on the peer review evaluation criteria published in the appropriate PA. The panel members used a scale of 10 to 1, with 10 representing the highest merit and 1 the lowest merit, using whole numbers only. The purpose of obtaining the criteria ratings was 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, panel members used a range of 1.0 to 5.0 (1.0 representing the highest merit and 5.0 the lowest merit), with scoring permitted in 0.1 increments. The BCRP averaged the panel member scores and rounded them to arrive at a two-digit number (1.2, 1.9, 2.7, etc.) that corresponds to the following adjectival equivalents 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. The BCRP staff used this document to report the peer review results to the Programmatic Panel. In accordance with USAMRDC policy, Summary Statements are available to each applicant after completion of the review process.

THE SECOND TIER—Programmatic Review

The FY24 Programmatic Panel conducted programmatic review in February 2025. The panel included a diverse group of basic and clinical scientists and consumer advocates, each of whom contributed 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 received high scores in the technical merit review process; rather, they closely examine the eligible applications to allocate as wisely as possible the limited funds available.

The 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).

The programmatic review criteria published in the Breakthrough Award Level 4 PA for stage 1 were as follows: ratings and evaluations of the peer reviewers; adherence to the intent of the funding opportunity; program portfolio composition and relative clinical impact. For stage 2 (oral presentation), the criteria were as follows: understanding of barriers to overcome in the overarching challenge selected/identified; articulation of a realistic vision for transitioning the results of the project into a near-term clinical impact for individuals with, or at risk for, breast cancer; and capability to lead efforts to transform and revolutionize the clinical management and/or prevention of breast cancer.

The 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.

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