

**US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS
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 six award mechanisms released in February 2023:

- Era of Hope Scholar Award
- Clinical Research Extension Award
- Breakthrough Award Level 3
- Breakthrough Award Level 4
- Innovator Award
- Transformative Breast Cancer Consortium Award

In response to the Era of Hope Scholar Award PA, eight compliant applications were received in April 2023 and peer reviewed in June 2023. Programmatic Review (Stage 1) was conducted in August 2023, and the Principal Investigator (PI) of one application was invited to Stage 2 programmatic review (oral presentation). One application (12.5%) was recommended for funding after Stage 2 programmatic review in November 2023 for a total of \$4.3 million (M).

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

In response to the Clinical Research Extension Award PA, five compliant applications were received, and two applications (40.0%) were recommended for funding for a total of \$15.7M.

Pre-applications were received for the Breakthrough Award Level 3, Breakthrough Award Level 4, Innovator Award, and Transformative Breast Cancer Consortium Award PAs in March 2023 and screened in April 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 Transformative Breast Cancer Consortium Award PA, no compliant pre-applications were received, and none were invited to submit a full application.

Applications were received for the Breakthrough Award Level 3, Breakthrough Award Level 4, and Innovator Award PAs in June 2023 and peer reviewed in August 2023. Breakthrough Award Level 3 programmatic review was conducted in November 2023. Breakthrough Award Level 4 and Innovator Award Stage 1 programmatic review was conducted in November 2023.

In response to the Breakthrough Award Level 3 PA, 38 pre-applications were received, and the PIs of 20 of these were invited to submit a full application. Eleven compliant applications were received, and none were recommended for funding.

In response to the Breakthrough Award Level 4 PA, five pre-applications were received, and the PIs of one of these was invited to submit a full application. One compliant application was received, and none were recommended for Stage 2 programmatic review (oral presentation).

In response to the Innovator Award PA, 17 pre-applications were received, and the PIs of two of these were invited to submit a full application. Two compliant applications were received, and none were recommended for Stage 2 programmatic review (oral presentation).

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

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

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Breakthrough Award Level 3	38	20 (52.6%)	11	0 (0%)	\$0.0M
Clinical Research Extension Award	N/A ⁺	N/A ⁺	5	2 (40.0%)	\$15.7M
Era of Hope Scholar Award	N/A ⁺	N/A ⁺	8	1 (12.5%)	\$4.3M
Total	38	20 (52.6%)	24	3 (12.5%)	\$20.0M

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

⁺N/A: Not applicable. PIs submitting to the Clinical Research Extension Award and Era of Hope Scholar Award PAs were not required to submit a pre-application to be screened; they were only required to submit a letter of intent.

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
Breakthrough Award Level 4	5	1 (20.0%)	1	0
Innovator Award	17	2 (11.8%)	2	0
Total	22	3 (13.6%)	3	0

*These data reflect recommendations only for mechanisms for which compliant applications were received.

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

Era of Hope Scholar Award applications were peer reviewed in June 2023 by one panel of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PA.

Breakthrough Award Level 3, Breakthrough Award Level 4, Clinical Research Extension Award, and Innovator Award applications were peer reviewed in August 2023 by four panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

Each peer review panel included a Chair, an average of five scientific reviewers, an average of one consumer reviewer, 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 (Clinical Research Extension Award, Breakthrough Award Level 3, Breakthrough Award Level 4): 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 (Clinical Research Extension Award, Breakthrough Award Level 3, Breakthrough Award Level 4): 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).

In contrast to the typical technical merit review process, no criteria scores were assigned to the Era of Hope Scholar Award and 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 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 Era of Hope Scholar Award (Stage 2), Clinical Research Extension Award, Breakthrough Award Level 3, Breakthrough Award Level 4 (Stage 1), and Innovator Award (Stage 1) was conducted in November 2023 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 Era of Hope Scholar Award and Innovator Award PAs 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 of 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.

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; programmatic relevance to the FY23 BCRP Overarching Challenges; and relative clinical impact.

Programmatic review criteria published in the Breakthrough Award Level 3 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 Breakthrough Award Level 4 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; and relative clinical impact. For Stage 2, the criteria include: 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.

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