US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2022 (FY22) RECONSTRUCTIVE TRANSPLANT RESEARCH PROGRAM (RTRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY22 RTRP called for applications in response to program announcements (PAs) for three award mechanisms released in June 2022:

- Investigator-Initiated Research Award (IIRA)
- Advanced Technology Development Award (ATDA)
- Concept Award (CA)

The FY22 RTRP additionally called for applications in response to one additional award mechanism which was released in December 2022:

- Clinical Network Award (CNA)

Pre-applications were received for the IIRA and ATDA PAs in July 2022 and were administratively reviewed in August 2022 to determine which investigators would be invited to submit a full application.

Applications for the IIRA and ATDA PAs were received in October 2022 and peer reviewed in December 2022. Programmatic review was conducted in February 2023. A second programmatic review is scheduled to take place in March 2023 to review the applications for the CA and the CNA.

In response to the IIRA PA, 20 pre-applications were received, and the Principal Investigators (PIs) of 20 of these were invited to submit a full application. Nineteen compliant applications were received, and four (21.1%) were recommended for funding for a total of $5.49 million (M).

In response to the ATDA PA, seven pre-applications were received, and the PIs of six of these were invited to submit a full application. Five compliant applications were received, and one (20.0%) was recommended for funding for a total of $1.50M.

Submission and award data for the FY22 RTRP are summarized in the table(s) below.

Table 1. Submission/Award Data for the FY22 RTRP[a]

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
IIRA	20	20 (100%)	19	4[b] (21.1%)	$5.49M
ATDA	7	6 (85.7%)	5	1[c] (20.0%)	$1.50M

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Total	**27**	**26 (96.3%)**	**24**	**5[d] (20.8%)**	**$6.99M**

[a] These data reflect funding recommendations only. Pending FY22 award negotiations, final numbers will be available after September 30, 2023.
[b] Four projects representing nine separate awards.
[c] One project representing two separate awards.
[d] Five projects representing 11 separate awards.

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Table 3. FY22 RTRP Application Data by Focus Area

Focus Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
ATDA: Tissue preservation for translation to the clinic	1	0	$0
ATDA: Tissue preservation impacts on vascularized composite allotransplantation (VCA) immunogenicity	1	0	$0
ATDA: Non-invasive monitoring - Validate reliable non-invasive biomarkers	0	0	$0
ATDA: Non-invasive monitoring - Develop assays or devices	3	1[a]	$1.50M
IIRA: Immunosuppression - Unique manifestations/mechanisms of VCA immunogenicity	1	0	$0
IIRA: Immunosuppression - Novel approaches for tolerance	13	4[b]	$5.49M
IIRA: Immunosuppression - Less-toxic and/or personalized regimens	1	0	$0
IIRA: Immunosuppression - Unique immunosuppression requirements	0	0	$0
IIRA: Non-invasive monitoring - Identify/validate reliable biomarkers	2	0	$0
IIRA: Non-invasive monitoring - Develop assays or devices	1	0	$0
IIRA: Outcome measures - Measures of clinical outcomes	0	0	$0
IIRA: Outcome measures - Measures of functional outcomes	0	0	$0
IIRA: Outcome measures - Measures of social outcomes	1	0	$0
Totals	**24**	**5[c]**	**$6.99M**

[a] One project representing two separate awards.
[b] Four projects representing nine separate awards.
[c] Five projects representing 11 separate awards.

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

IIRA and ATDA applications were peer reviewed in December 2022 by two panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

Peer review was conducted via videoconference for the IIRA and ATDA by two panels (21 scientists and two consumer reviewers).

Each peer review panel included a Chair, an average of 10 scientific reviewers, 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 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 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 essence of the 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 was conducted in February 2023 by the FY22 Programmatic Panel, which is comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in reconstructive transplants. 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. The programmatic review criteria published in the PAs were as follows: ratings and evaluations of the scientific peer review panels; programmatic relevance; relative impact and military relevance; program portfolio composition; relevance to the FY22 RTRP Focus Areas; and adherence to the intent of the award mechanism. After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.