US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2022 (FY22) RECONSTRUCTIVE TRANSLPLANT
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, as well as a program announcement for an award mechanism released in December 2022, for a total of four award mechanisms:

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

Applications for the IIRA and ATDA were programmatically reviewed in February 2023 after going through peer review in December 2022. Applications for the CA PA were received in October 2022 and peer reviewed in February and March 2023. Applications for the CNA were received in February 2023 and peer reviewed in March 2023. A second programmatic review was conducted in March 2023 to review applications for the CA and the CNA.

In response to the CA PA, twelve compliant applications were received, and 2 (16.7%) were recommended for funding for a total of $0.4M.

In response to the CNA PA, two compliant applications were received, and one (50%) was recommended for funding for a total of $3.0M*.

Submission and award data for the FY22 RTRP's second programmatic review are summarized in the tables below.

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

Mechanism	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
CA	12	2 (16.7%)	$0.40M
CNA	2	1 (50%)	$3.00M*
Total	**14**	**3 (21.4%)**	**$3.40M**

[a] These data reflect funding recommendations only for the CA and CNA applications. Pending FY22 award negotiations, final numbers will be available after September 30, 2023.

*Reflects funding for phase one of project.

Table 2. FY22 RTRP Application Data by Focus Area

Focus Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
CA: Reduce the risks of VCA-associated immunosuppression - Define the unique manifestations and/or mechanisms of VCA immunogenicity	3	1	$0.2M
CA: Reduce the risks of VCA-associated immunosuppression - Develop novel approaches for achieving VCA immune tolerance	5	1	$0.2M
CA: Reduce the risks of VCA-associated immunosuppression - Develop less-toxic and/or personalized regimens for maintenance immunosuppression	3	0	$0
CA: Reduce the risks of VCA-associated immunosuppression - Identify unique immunosuppression requirements for VCA compared to other solid organ transplants	1	0	$0M
CA: Identify reliable non-invasive prognostic/diagnostic biomarkers, methods, or tools for monitoring VCA graft rejection - Identify new peripheral biomarkers for acute and chronic VCA graft rejection	0	0	$0M
CA: Identify reliable non-invasive prognostic/diagnostic biomarkers, methods, or tools for monitoring VCA graft rejection - Develop assays or devices for clinical implementation of graft monitoring utilizing validated biomarkers	0	0	$0M
CNA: Patient inclusion/exclusion criteria, patient education, surgical procedures, immunosuppression and/or immunoregulation, outcome metrics, quality of life measures, rehabilitation, patient reporting (e.g., registry)	2	1	$3.0M
Totals	**14**	**3**	**$3.4M**

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

CA and CNA applications were peer reviewed in February and March 2023, respectively, by three panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs. These panels included 17 scientist reviewers and 3 consumer reviewers.

Each peer review panel included a Chair, one consumer reviewer, and an average of six scientific reviewers. The primary responsibility of the panelists was to review the technical merit of each application based on 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: For CNA applications, 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. Applications for the CA did not receive scores for individual criteria.

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, the peer reviewers' written comments, and the 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

The RTRP's second programmatic review was conducted in March 2023 by the FY22 Programmatic Panel, which was 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.

Concept Award:
The programmatic review criteria published in the PA were as follows: Ratings and evaluations of the peer reviewers; relevance to the mission of the Defense Health Program and FY22 RTRP as evidenced by adherence to the intent of the award mechanism, program portfolio composition, programmatic relevance to the CA Focus Areas, and relative innovation and military relevance.

Clinical Network Award:
As described in the research announcement, programmatic review for the CNA was composed of two parts, each with its own set of review criteria.
Stage 1: Ratings and evaluations of the peer reviewers; relevance to the mission of the FY22 RTRP as evidenced by adherence to the intent of the award mechanism, program portfolio composition, programmatic relevance to the CNA Focus Areas, relative impact and military relevance.
Stage 2: Applicants gave a 30-minute oral presentation which was followed by a question-and-answer session with the programmatic panel. The criteria for stage 2 were as follows:
• How well institutional support, cost share opportunities, and available facilities and resources will facilitate successful completion of Clinical Network objectives.
• How well plans for collaboration and communication will be promoted among Network Sites to facilitate achievement of objectives.
• How well financial compensation to Network Sites will be managed for participation in Phase 1 (protocol/CPG development) and Phase 2 (Clinical Trials) of the Clinical Network.
• How equitably plans to develop standardized protocols and CPGs support a fair and unbiased process, and how effectively conflicts will be addressed.
• How effectively plans for clinical trial recruitment support maximum enrollment across Network Sites, and how inclusive the outreach strategy will be of military, Veteran, and civilian populations, as well as women and minorities.

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