

**US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2021 (FY21) RECONSTRUCTIVE TRANSPLANT
RESEARCH PROGRAM (RTRP)**

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY21 RTRP called for applications in response to program announcements (PAs) for two award mechanisms released in August 2021:

- Investigator-Initiated Research Award (IIRA)
- Advanced Technology Development Award (ADTA)

Pre-applications were received for these two PAs in September 2021 and screened in October 2021 to determine which investigators would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the PAs.

Applications were received for these two PAs in December 2021 and peer reviewed in January 2022. Programmatic review was conducted in April 2022.

In response to the IIRA PA, 37 pre-applications were received, and the Principal Investigators (PIs) of 28 of these were invited to submit a full application. Twenty-five compliant applications were received, and five (20.0%) were recommended for funding for a total of \$7.5 million (M).

In response to the ATDA PA, 13 pre-applications were received, and the PIs of 9 of these were invited to submit a full application. Eight compliant applications were received, and three (37.5%) were recommended for funding for a total of \$4.0M.

Submission and award data for the FY21 RTRP are summarized in the table(s) below.

Table 1. Submission/Award Data for the FY21 RTRP^a

| Mechanism | Pre-Applications Received | Pre-Applications Invited (%) | Compliant Applications Received | Applications Recommended for Funding (%) | Total Funds |
|------------------|----------------------------------|-------------------------------------|--|---|--------------------|
| IIRA | 37 | 28 (75.7%) | 25 | 5 ^b (20.0%) | \$7.5M |
| ADTA | 13 | 9 (69.2%) | 8 | 3 ^c (37.5%) | \$4.0M |
| Total | 50 | 37 (74.0%) | 33 | 8^d (24.2%) | \$11.5M |

^a These data reflect funding recommendations only. Pending FY21 award negotiations, final numbers will be available after September 30, 2022.

^b Five projects representing 12 separate awards.

^c Three projects representing five separate awards.

^d Eight projects representing 17 separate awards.

Table 3. FY21 RTRP Application Data by Focus Area

| Focus Area | Compliant Applications Received | Applications Recommended for Funding (%) | Total Funds |
|---|--|---|--------------------|
| ATDA: Tissue preservation –impacts on VCA immunogenicity. | 1 | 0 | \$0 |
| ATDA: Tissue preservation –translation to the clinic. | 5 | 2 ^a | \$2.5M |
| ATDA: Non-invasive monitoring– Biomarkers for chronic rejection | 1 | 1 ^b | \$1.5M |
| ATDA: Non-invasive monitoring– Validate new peripheral biomarkers | 1 | 0 | \$0 |
| ATDA: Non-invasive monitoring– Develop assays or devices | 1 | 0 | \$0 |
| IIRA: Non-invasive monitoring – Develop reliable biomarkers | 1 | 1 ^c | \$1.5M |
| IIRA: Non-invasive monitoring – Identify/validate new biomarkers | 2 | 1 ^d | \$1.5M |
| IIRA: Immunosuppression – unique manifestations/mechanisms of VCA immunogenicity. | 6 | 1 ^e | \$1.5M |
| IIRA: Immunosuppression –less-toxic regimens | 3 | 0 | \$0 |
| IIRA: Immunosuppression –unique immunosuppression requirements | 0 | 0 | \$0 |
| IIRA: Immunosuppression –novel approaches for tolerance. | 10 | 2 ^f | \$3.0M |
| IIRA: Retrospective studies –rejection episodes/treatment interventions/complications | 0 | 0 | \$0 |
| IIRA: Retrospective studies –VCA outcomes compared to prosthesis users. | 0 | 0 | \$0 |
| IIRA: Retrospective studies – VCA/SOT comparison of protocols and outcomes | 1 | 0 | \$0 |
| IIRA: Retrospective studies – Assessment of VCAs performed to date | 1 | 0 | \$0 |
| Totals | 33 | 8^g | \$11.5M |

^a Two projects representing three separate awards.

^b One project representing two separate awards.

^c One project representing two separate awards.

^d One project representing three separate awards.

^e One project representing two separate awards.

^f Two projects representing five separate awards.

^g Eight projects representing 17 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 January 2022 by three panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs. Across these three panels were 23 scientist reviewers, 3 consumer reviewers, and 3 scientific review officers.

Peer review was conducted via videoconference for the IIRA and ADTA by three panels (26 scientists and 3 consumer reviewers).

Each peer review panel included a Chair, an average of seven 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, 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

Programmatic review was conducted in April 2022 by the FY21 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. 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 FY21 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.