US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2021 (FY21) GULF WAR ILLNESS RESEARCH PROGRAM (GWIRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY21 GWIRP called for applications in response to program announcements (PAs) for five award mechanisms released in March 2021:

- Therapeutic/Biomarker Trial Award (TBTA)
- Clinical Evaluation Award (CEA)
- Research Advancement Award (RAA)
- Idea Award (IA)
- New Investigator Award (NIA)

Pre-applications were received for these five PAs in May 2021 and screened in June 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 five PAs in August 2021 and peer reviewed in October 2021. Programmatic review was conducted in January 2022.

In response to TBTA PA, two pre-applications were received and the Principal Investigator (PI) of one was invited to submit a full application. One compliant application was received and it was recommended for funding for a total of \$6.37 million (M).

In response to the CEA PA, 10 pre-applications were received and the PIs of 7 of these were invited to submit a full application. Five compliant applications were received and three (60%) were recommended for funding for a total of \$6.04M.

In response to the RAA PA, 20 pre-applications were received and the PIs of 15 of these were invited to submit a full application. Fourteen compliant applications were received and five (36%) were recommended for funding for a total of \$4.27M.

In response to the IA PA, 28 pre-applications were received and the PIs of 21 of these were invited to submit a full application. Twenty-one compliant applications were received and one (5%) was recommended for funding for a total of \$0.29M.

In response to the NIA PA, 29 pre-applications were received and the PIs of 22 of these were invited to submit a full application. Twenty compliant applications were received and one (5%) was recommended for funding for a total of \$0.72M.

Submission and award data for the FY21 GWIRP are summarized in the table below.

Applications Compliant Pre-Pre-Recommended **Total Applications** Mechanism **Applications Applications** for Funding Funds Received **Invited (%)** Received (%) **TBTA** 2 1 (50%) 1 (100%) \$6.37M 1 7 (70%) **CEA** 10 5 3 (60%) \$6.04M 5 (36%) RAA 20 15 (75%) 14 \$4.27M IΑ 28 21 (75%) 21 1 (5%) \$0.29M 29 22 (76%) **NIA** 20 1 (5%) \$0.72M **Total** 89 66 (74%) 61 11 (18%) \$17.69M

Table 1. Submission/Award Data for the FY21 GWIRP*

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

TBTA, CEA, RAA, IA, and NIA applications were peer reviewed in October 2021 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, scientific reviewers, consumer reviewers, 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.

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

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 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 was conducted in January 2022 by the FY21 Programmatic Panel that was comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in Gulf War Illness. 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 PAs are tabulated in Table 2 below:

Table 2. Programmatic Review Criteria for the FY21 GWIRP

Mechanism				
TBTA	CEA	RAA	IA	NIA
Programmatic Review Criteria				
Ratings and evaluations of the peer reviewers				
Adherence to the intent of the award mechanism				
Relative impact				
Program portfolio composition				
Relative outcomes from the PI's previous GWI-related research, if applicable				
			Relative	
			innovation	

After programmatic review, the Commanding General, USAMRDC, approved funding for the applications recommended during programmatic review.