US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2023 (FY23) KIDNEY CANCER RESEARCH PROGRAM (KCRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY23 KCRP called for applications in response to program announcements (PAs) for six award mechanisms released in June and July 2023:

- Academy of Kidney Cancer Investigators Early-Career Scholar Award
- Clinical Consortium Award
- Clinical Trial Award
- Idea Development Award
- Nurse-Initiated Research Award
- Translational Research Partnership Award

Pre-applications (Letters of Intent [LOIs]) were received for the Academy of Kidney Cancer Investigators – Early-Career Scholar Award, Clinical Trial Award, Idea Development Award, Nurse-Initiated Research Award, and Translational Research Partnership Award PAs in September 2023.

Pre-applications (LOIs) were received for the Clinical Consortium Award PA in October 2023.

Applications were received for the Academy of Kidney Cancer Investigators – Early-Career Scholar Award, Clinical Trial Award, Idea Development Award, Nurse-Initiated Research Award, and Translational Research Partnership Award PAs in October 2023 and peer reviewed in December 2023 – January 2024. Programmatic review was conducted in March 2024.

Applications were received for the Clinical Consortium Award PA in November 2023 and peer reviewed in January 2024. Programmatic review was conducted in March 2024.

In response to the Academy of Kidney Cancer Investigators – Early-Career Scholar Award PA, 12 compliant applications were received and four (33.3%) were recommended for funding for a total of \$4.50 million (M).

In response to the Clinical Consortium Award PA, seven compliant applications were received and seven (100%) were recommended for funding for a total of \$5.97M.

In response to the Clinical Trial Award PA, six compliant applications were received and one (16.7%) was recommended for funding for a total of \$2.12M.

In response to the Idea Development Award PA, 94 compliant applications were received and 17 (18.1%) representing 24 potential awards were recommended for funding for a total of \$26.18M.

In response to the Nurse-Initiated Research Award PA, no compliant applications were received.

In response to the Translational Research Partnership Award PA, 14 compliant applications were received and three (21.4%) representing six potential awards were recommended for funding for a total of \$3.16M.

Submission and award data for the FY23 KCRP are summarized in the table below.

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

Mechanism	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Academy of Kidney Cancer Investigators – Early-Career Scholar Award	12	4 (33.3%)	\$4.50M
Clinical Consortium Award	7	7 (100%)	\$5.97M
Clinical Trial Award	6	1 (16.7%)	\$2.12M
Idea Development Award	94 representing 139 potential awards	17 (18.1%) representing 24 potential awards	\$26.18M
Nurse-Initiated Research Award	0	_	_
Translational Research Partnership Award	14 representing 28 potential awards	3 (21.4%) representing 6 potential awards	\$3.16M
Total	133 representing 192 potential awards	32 (24.1%) representing 42 potential awards	\$41.93M

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

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

Academy of Kidney Cancer Investigators - Early Career Scholar Award, Clinical Research Nurse Development Award, Clinical Trial Award, Idea Development Award, Translational Research Partnership Award, and Clinical Consortium Award applications were peer reviewed in December 2023 and January 2024 by seven panels of researchers, clinicians, and consumer

advocates based on the evaluation criteria specified in the PAs. Following the submission of reviewer scores, a moderated online discussion feature was available to reviewers if there was discrepancy in scoring.

Each peer review panel included a Chair, an average of eight 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: 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 February 2024 by the FY23 Programmatic Panel, comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in kidney 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 PAs were as follows: ratings and evaluations of the scientific peer review panels; programmatic relevance to the FY23 KCRP Focus Areas and alignment with the Overarching Strategic Goals; relative [clinical (Clinical Trial Award only)] impact and innovation (Idea Development Award only); program portfolio composition and balance (Academy of Kidney Cancer – Early-Career Scholar Award, Clinical Trial Award, and Nurse-Initiated Research Award only); partnership and synergy (Translational Research Partnership Award only); adherence to the intent of the award mechanism; and addressing a critical problem in kidney cancer patient care (Clinical Trial Award only). After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.