REPORT TO THE U.S. CONGRESS

U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

PEER REVIEWED CANCER RESEARCH PROGRAM

Peer Reviewed Cancer Research Program Report to Congress

TABLE OF CONTENTS

Background and Purpose of Report	3
FY09-10 Peer Reviewed Cancer Research Program	4
FY11 Peer Reviewed Cancer Research Program	5
References	7

BACKGROUND and PURPOSE OF REPORT

The U.S. Army Medical Research and Materiel Command (USAMRMC) is a major subordinate Command of the United States Army Medical Command. The USAMRMC manages biomedical research and development programs of the Defense Health Program from the Department of Defense (DOD). The Commanding General (CG), USAMRMC, is assigned authority as the Executive Agent for a number of medical research, development, and acquisition programs. Congressional appropriations totaling over \$6 billion for fiscal years 1992 to 2010 (FY92-10) have been assigned to the Office of the Congressionally Directed Medical Research Programs (CDMRP), a subordinate organization within the USAMRMC. Biomedical research supported by these funds includes research in breast, prostate, lung, ovarian, melanoma and genetic cancers; pediatric brain tumors, neurofibromatosis; tuberous sclerosis complex; autism; Gulf War illness; psychological health and traumatic brain injury; deployment-related medical; and other conditions. The CDMRP is responsible for planning, coordinating, integrating, programming, budgeting, and executing these research programs.

Following receipt of appropriations, each program's Integration Panel, an external advisory board of leading scientists, clinicians, military members, and survivors of the disease, condition, or injury (consumers), recommends an investment strategy for the upcoming year that meets the unique needs of the research field, consumer community, and the military. By revisiting the investment strategy yearly, the program is able to explore innovative scientific ideas and research gaps spanning from basic laboratory science to clinical trials. Program announcements requesting research applications through specific award mechanisms are subsequently prepared and released. Integration Panel members are not allowed to be involved either as collaborators or participants in the application processes including, but not limited to, concept design, application development, and conduct of research.

To ensure that each program's research portfolio reflects not only the most meritorious science, but also the most programmatically relevant research, the CDMRP developed a unique application review model based upon recommendations from the Institute of Medicine (IOM) 1993 report. The IOM suggested a two-tier review procedure for research applications composed of a scientific peer review and a separate programmatic review. The scientific peer review is conducted by an external panel of scientists, clinicians, service members, and consumers recruited specifically for each peer review session. Each application is evaluated based on criteria delineated in the program announcements. The second tier of review, the programmatic review, is conducted by the Integration Panel. The Integration Panel reviews the applications based on the scientific peer review ratings, a balanced portfolio, programmatic intent, and relevance to the congressional language. Scientifically sound applications that best meet the program's interests and goals are recommended to and approved by the CG, USAMRMC, for funding. Awards are then made in the form of 1- to 5-year grants, contracts, or cooperative agreements, and assigned to CDMRP Science Officers for full-cycle support of research and outcomes. The USAMRMC and CDMRP have been praised by the IOM, which

issued a report in 1997 stating it was favorably impressed with the processes implemented by the CDMRP and supported its continuation.²

In Public Law 110-329 from the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009, a "peer-reviewed cancer research program" was appropriated for \$16 million (M). In November 2008, the Peer Reviewed Cancer Research Program (PRCRP) was assigned to the USAMRMC and to the CDMRP for execution by the Assistant Secretary of Defense for Health Affairs, Force Health Protection. Public Law 111-118 from the 2010 Defense Appropriations Act directed funding of \$15M. In April 2011, Public Law 112-10 from the Department of Defense and Full Year Continuing Appropriations Act directed \$16M for the PRCRP. The Congressional Record of the Senate dated 14 December 2010 required that the DOD issue a report on the status of the PRCRP. This report details the status of the FY09-11 PRCRP and the relevance of this type of research for service members and their families.

Cancer care has a significant impact on the military. The Veterans Health Administration (VHA) acknowledged the toll of cancer on service members and their families when releasing its National Cancer Strategy in 2003 (VHA-Directive 2003-34). There are over 350,000 military beneficiaries with a cancer diagnosis, for a prevalence of 4.1%, comprised of over 60 different cancer types.³ The estimated cost of cancer care within the Military Health System in FY02 was over \$1 billion.³ Funding research on the detection, diagnosis, treatment, and prevention of these diseases benefits both the warfighter and the American public, ultimately leading to increased survival rates and decreased costs of medical care.

FY09-10 PEER REVIEWED CANCER RESEARCH PROGRAM

Public Law 110-329 from the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009, directed that \$16M be appropriated for the FY09 PRCRP. The funds and directed research topic areas included: \$4M for melanoma and other skin cancers as related to deployments of service members to areas of high exposure; \$2M for pediatric brain tumors within the field of childhood cancer research; \$8M for genetic cancer and its relation to exposure to the various environments that are unique to a military lifestyle; and \$2M for noninvasive cancer ablation treatment including selective targeting with nano-particles. An inaugural stakeholders meeting was held on 23-24 February 2009 that included leading scientists, clinicians, military members, and consumers. Working groups from each topic area discussed gaps in scientific knowledge and research, consumer concerns, and military medicine. The Integration Panel was established in April 2009 to conduct vision setting to review the recommendations made at the stakeholders meeting, to craft a vision and mission of the program, and to develop an investment strategy. The vision of the FY09 PRCRP was to improve quality of life by significantly decreasing the impact of cancer on service members, their families, and the American public. To attain this goal, the FY09 PRCRP mission was to foster groundbreaking research, team science, and partnerships for the development of better prevention, earlier detection, and more effective treatments for cancer. Several program announcements were released in June 2009. Following the two levels of review, 38 awards across the four different topic areas were approved by the CG, USAMRMC. The research portfolio of the FY09 PRCRP included epidemiology, immunology, pathobiology, genetics and

molecular biology, clinical and experimental therapeutics, cell biology, detection and diagnosis, and research resources.

In FY10, Public Law 111-118 from the 2010 Defense Appropriations Act directed funding of \$15M for a "peer reviewed cancer research program" that would research cancers not addressed in the breast, prostate, lung, and ovarian cancer research programs currently executed by the DOD and, specifically, the USAMRMC. Specific topics included melanoma and other skin cancers, pediatric brain tumors within the field of childhood cancer research, genetic cancer research and genomic medicine, kidney cancer, blood cancer, colorectal cancer, *Listeria* vaccine for cancer, and radiation protection utilizing nanotechnology.

An Integration Panel consisting of members of the FY09 PRCRP Integration Panel and new members to represent the congressional target areas was convened in March 2010. The Integration Panel recommended the vision of the FY10 PRCRP remain unchanged, but that the mission be revised: to foster groundbreaking and collaborative research to accelerate progress in cancer prevention, detection, and therapeutic interventions. FY10 focus areas were defined for each topic area. Program announcements were released in May and June 2010. Relevance to military beneficiaries was required and reviewed at both peer and programmatic review. Following the two levels of review, 32 awards across the different topic areas were approved by the CG, USAMRMC. Final award agreements for the FY10 PRCRP are expected to be in place no later than 30 September 2011.

FY11 PEER REVIEWED CANCER RESEARCH PROGRAM

For FY11, Public Law 112-10 from the Department of Defense and Full Year Continuing Appropriations Act directed \$16M for the PRCRP. The Congressional Record of the Senate dated 14 December 2010 specified topics areas of melanoma and other skin cancers, pediatric cancer research, genetic cancer research, kidney cancer, blood cancer, colorectal cancer, pancreatic cancer, mesothelioma, *Listeria* vaccine for infectious disease and cancer, and radiation protection utilizing nanotechnology. This was later revised to remove *Listeria* vaccine for infectious disease. Further clarification acknowledged the requirement for relevance to service members and their families and that the funding would be directed toward research on cancers not addressed in the breast, prostate, lung (with the exception of mesothelioma), and ovarian cancer research programs currently executed by the DOD and, specifically, the USAMRMC.

Vision setting was held on 19 April 2011. The FY11 Integration Panel consisting of members of the FY10 PRCRP Integration Panel and new members to represent the congressional target areas was convened to discuss research gaps, community needs, focus areas, and an investment strategy. Program announcements will be released in June 2011. Receipt for preproposals will be in late July 2011, with a preproposal screening meeting in September 2011. Full application receipt will be in November 2011. Peer review is planned for January 2012 and programmatic review is planned for March 2012. The final recommendation for funding list will be sent to the CG, USAMRMC for approval and grant negotiations will ensue. Final award agreements for the FY11 PRCRP are expected no later than 30 September 2012.

Peer Reviewed Cancer Research Program Fiscal Year 2011 Report to Congress

In summary, the CDMRP, USAMRMC, manages the FY09-11 PRCRP using its established and highly recognized management process. Members of the various services will provide input and recommendations throughout the programmatic cycle for PRCRP. The CDMRP will plan, execute, and manage the FY09-11 PRCRP with the same rigor and integrity it has demonstrated for other research programs.

REFERENCES

- 1. Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command (1993) Committee to Advise the Department of Defense on Its Fiscal Year 1993 Breast Cancer Program, Institute of Medicine, National Academy Press, Washington, DC.
- 2. A Review of the Department of Defense's Program for Breast Cancer Research (1997) Committee to Review the Department of Defense's Breast Cancer Research Program, Institute of Medicine, National Academy Press, Washington, DC.
- 3. Crawford RS, Wu J, Park D, and Barbour GL. 2007. A study of cancer in the military beneficiary population. *Military Medicine* 172:1084-1088.