OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

The Honorable Carl Levin
Chairman, Committee on Armed Services
United States Senate
Washington, DC 20510

JUN 09 2009

Dear Mr. Chairman:

The enclosed report is submitted in response to the Joint Explanatory Statement for H. R. 2638/Public Law 110-329, which requested the Secretary of Defense provide a report to the congressional defense committees no later than 120 days after enactment that describes a plan for Peer-Reviewed Lung Cancer Research and includes Walter Reed Army Medical Center in the formulation of this plan.

We are pleased to provide the final report with the plan for execution and management of the fiscal year 2009 funds for Peer-Reviewed Lung Cancer Research. The U.S. Army Medical Research and Materiel Command (USAMRMC) will manage the $20 million appropriation using its established execution and management cycle. The following time line is anticipated: stakeholders meeting in February 2009; program announcements in May 2009; an external scientific peer review to evaluate proposals in October 2009; the integrated Joint Programmatic Committee review in December 2009; and awards completed by September 2010. USAMRMC will plan, execute, and manage the fiscal year 2009 Peer-Reviewed Lung Cancer Research funds with the same rigor and integrity as it has done in the past.

Thank you for your continued support of the Military Health System.

Sincerely,

Ellen P. Embrey
Performing the Duties of the
Assistant Secretary of Defense
(Health Affairs)

Enclosure:
As stated

cc:
The Honorable John McCain
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

The Honorable Ben Nelson
Chairman, Subcommittee on Personnel
Committee on Armed Services
United States Senate
Washington, DC 20510

JUN 09 2009

Dear Mr. Chairman:

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Performing the Duties of the
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(Health Affairs)

Enclosure:
As stated

cc:
The Honorable Lindsey O. Graham
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

The Honorable Daniel K. Inouye
Chairman, Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

JUN 09 2009

Dear Mr. Chairman:

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(Health Affairs)

Enclosure:
As stated

cc:
The Honorable Thad Cochran
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

JUN 09 2009

The Honorable Ike Skelton
Chairman, Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Ellen P. Embrey
Performing the Duties of the
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(Health Affairs)

Enclosure:
As stated

cc:
The Honorable John M. McHugh
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

JUN 09 2009

The Honorable Susan Davis
Chairwoman, Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

The enclosed report is submitted in response to the Joint Explanatory Statement for House Report 2638/Public Law 110-329, which required that the Secretary of Defense provide a report to the congressional defense committees no later than 120 days after enactment that describes a plan for Peer-Reviewed Lung Cancer Research and includes Walter Reed Army Medical Center in the formulation of this plan.

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Ellen P. Embrey
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(Health Affairs)

Enclosure:
As stated

cc:
The Honorable Joe Wilson
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

JUN 09 2009

The Honorable John P. Murtha
Chairman, Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report is submitted in response to the Joint Explanatory Statement for H. R. 2638/Public Law 110-329, which requested the Secretary of Defense provide a report to the congressional defense committees no later than 120 days after enactment that describes a plan for Peer-Reviewed Lung Cancer Research and includes Walter Reed Army Medical Center in the formulation of this plan.

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Sincerely,

Ellen P. Embrey
Performing the Duties of the
Assistant Secretary of Defense
(Health Affairs)

Enclosure:
As stated

cc:
The Honorable C. W. Bill Young
Ranking Member

# REPORT TO CONGRESS

# U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

# CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

LUNG CANCER RESEARCH PROGRAM

28 January 2009

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## BACKGROUND and PURPOSE OF REPORT

At the direction of the United States Congress, the Department of Defense manages targeted biomedical research. The U.S. Army Medical Research and Materiel Command (USAMRMC) is responsible for administering many of these appropriations. The USAMRMC is a major subordinate Command of the United States Army Medical Command. 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 $4.8 billion for fiscal year (FY) 92-08 assigned to USAMRMC are managed by the Congressionally Directed Medical Research Programs (CDMRP) office (a subordinate organization to the USAMRMC). The research programs supported by these funds include breast, prostate, and ovarian cancers; neurofibromatosis; autism; Gulf War illness; psychological health and traumatic brain injury; deployment-related medical; and other programs. The CDMRP is responsible for planning, coordinating, integrating, programming, budgeting, and executing these programs using a two-tier review process as recommended by the National Academy of Science's Institute of Medicine (10M) in its 1993 report[1]. The CDMRP's flexible 7-year execution and management cycle includes the receipt of annual congressional appropriations, stakeholders meeting, vision setting, proposal review, selection of grants for funding, and oversight of research grants. Briefly, following receipt of appropriations, each program's external advisory board of leading scientists, clinicians, and disease survivors (Integration Panel) develops an investment strategy for the upcoming year that meets the unique needs of the research field and encourages exploration of innovative, novel, and under-investigated areas spanning from basic laboratory science to clinical trials. Program announcements requesting research proposals through specific award mechanisms are subsequently prepared and released. Integration Panel members are not allowed to be involved as either collaborators or participants in the proposal processes including, but not limited to, concept design, proposal 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 proposal review model based upon recommendations from the IOM 1993 report[1]. The IOM

recommended a two-tier review procedure for research proposals composed of scientific (peer) review and a separate programmatic review. Scientifically sound proposals that best meet the program's interests and goals are recommended to the CG, USAMRMC, for funding. Once the CG approves the funding recommendations, awards are made in the form of 1-to 5-year grants, contracts, or cooperative agreements and assigned to Grants Managers for full cycle support of research grants and outcomes. The programs that comprise the CDMRP are scientifically sound, innovative, and responsive to congressional intent and the needs of the public. The USAMRMC and CDMRP have been praised by the 10M, which issued a report in 1997 stating it was favorably impressed with the CDMRP and supported its continuation.[2]

In the FY 09 Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, a Peer-Reviewed Lung Cancer Research Program was appropriated $20 million. The program was assigned by the Assistant Secretary of Defense for Health Affairs, Force Health Protection to USAMRMC and to the CDMRP in November 2008 for execution. The conferees requested that an execution plan for the FY 09 Peer-Reviewed Lung Cancer Research Program be provided to the congressional defense committees within 120 days after enactment of this Act. The current report details the status of the FY 09 Peer-Reviewed Lung Cancer Research Program.

## FY 09 LUNG CANCER RESEARCH PROGRAM

The FY 09 Consolidated Security, Disaster Assistance, and Continuing Appropriations Act conferees requested that the $20 million appropriated for the FY 09 Peer-Reviewed Lung Cancer Research Program be utilized to support competitive research and the establishment of a tissue bank. In addition, priority shall be given to the development of the integrated components to identify, treat, and manage early curable lung cancer. The Army is expected to provide a plan for these funds and to include the Walter Reed Army Medical Center in the formulation of this plan. Planning for this program is ongoing.

The first major milestone in the execution and management cycle of the Peer-Reviewed Lung Cancer Research Program is the stakeholders meeting, currently scheduled for February 2009. Renowned scientists and clinicians from academia and from other funding agencies, such as the National Cancer Institute and the Department of Veterans Affairs, and disease survivors from advocacies such as the Lung Cancer Alliance will be invited to the stakeholders meeting to discuss issues and gaps critical to lung cancer, as well as potential means to address them. Utilizing the recommendations from the stakeholders, the Lung Cancer Research Program Integration Panel, to be composed of experts in the lung cancer field and disease survivors, will assemble in March 2009 to assist in determining the vision and investment strategy for the FY 09 Lung Cancer Research Program. Representatives from the Walter Reed Army Medical Center will participate in both the stakeholders and vision setting meetings as Integration Panel members to assist in establishing program priorities and an investment strategy for the FY 09 program that most effectively addresses emerging needs and evolving priorities. These program priorities shall focus on areas that will move the field forward and may include gaps in knowledge of lung cancer; unfunded or underfunded approaches to identifying, treating, and managing early curable lung cancer; or resources needed to conduct research. The CDMRP staff will then prepare and release program announcements in May 2009 to request proposals from investigators interested in competing for funds to conduct research on the FY 09 Lung Cancer Research Program priorities. As mentioned previously, members of the Lung Cancer Research Program

Integration Panel are not allowed to participate in the design, development, or execution of a research proposal submitted to this program.

In keeping with the CDMRP's two-tier proposal review process recommended by the 10M, scientific (peer) review, the first level of review for the FY 09 Lung Cancer Research Program will be conducted in October 2009 by an external panel that includes scientific experts and lung cancer survivors. Peer review is a criterion-based process whereby proposals are judged on their own scientific and technical merit based on established evaluation criteria which are delineated in the program announcements. Scientists and clinicians from the Walter Reed Army Medical Center will be eligible to serve as scientific peer reviewers. The second tier of review, programmatic review, will be conducted in December 2009 by the same Integration Panel that will have assisted in establishing the program priorities and investment strategy. In contrast to the scientific peer review, the goal of programmatic review will be to develop funding recommendations based on the ratings and recommendations of scientific peer review that balance the most meritorious and innovative science across many disciplines and offer the highest promise for fulfilling the programmatic goals of the FY 09 Lung Cancer Research Program. As members of the FY 09 Lung Cancer Research Program Integration Panel, representatives from the Walter Reed Army Medical Center will participate in developing these funding recommendations.

In summary, the CDMRP, USAMRMC will manage the $20 million appropriation for the FY 09 Peer-Reviewed Lung Cancer Research Program using its established execution and management cycle and will include the Walter Reed Army Medical Center in the formulation of the plan for these funds. The following timeline is anticipated. A stakeholders meeting will take place in February 2009 with the vision setting and investment strategy meeting tentatively scheduled for March 2009. Program announcements requesting research proposals will be released in May 2009. Congressional language indicates that funds shall support competitive research and the establishment of a tissue bank, and priority shall be given to the development of the integrated components to identify, treat, and manage early curable lung cancer. An

external scientific peer review will evaluate proposals for scientific merit in October 2009, and the Integration Panel will programmatically review proposals in December 2009. Following programmatic review, award recommendations will be submitted to the CG, USAMRMC. Award negotiations will commence following the CG's approval and will be completed by September 2010. The CDMRP will plan, execute, and manage the FY 09 Peer-Reviewed Lung Cancer Research Program with the same rigor and integrity as it has done for other research programs in the past.

## 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, N