Public Health Subcommittee

Improving Defense Health Program Medical Research Processes

Defense Health Board
June 2, 2016
Overview

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Public Health Subcommittee

- 10 members including the Chair
“I request that the Defense Health Board (DHB) . . . provide recommendations to the Department regarding approaches that would optimally support military medical professionals who oversee and conduct DHP medical research.”

Request that the Defense Health Board address and develop findings and recommendations on the following:

- Determine how DoD may improve visibility on Defense Health Program (DHP) medical research supported through separate funding sources (RDT&E and O&M) to enhance coordination of effort, oversight, and collaboration.

- Determine the major challenges that DoD investigators face in initiating, funding, conducting, and publishing DHP medical research.

- Determine how DoD may facilitate more efficient initiation and conduct of high-quality DHP medical research without compromising safety or data protection standards.

(RDT&E = research, development, test & evaluation; O&M = operations and maintenance)
Request that the Defense Health Board address and develop findings and recommendations on the following:

- Determine how DoD may improve Institutional Review Board processes to facilitate more efficient approval of multicenter studies and clinical trials.

- Determine cost-effective mechanisms to encourage more professionals to become engaged in medical research.

- Determine mechanisms to improve acknowledgement in public communications by other government agencies and industry of DoD’s contributions to products it has funded or partially developed and subsequently handed off.
Timeline

Meetings Since Previous Board Meeting

- March 4, 2016 – Meeting at San Antonio Military Medical Center (SAMMC)
- April 19, 2016 – Teleconference
- May 17, 2016 – Meeting at Ft Detrick

Upcoming Meetings

- June & July 2016 – Teleconferences
- August 2016 – Military Health System Research Symposium
March 4, 2016
- Roundtable discussions at SAMMC with Army and Air Force clinical research leadership and senior/mid-career/junior investigators.

April 19, 2016
- Draft Report Materials Discussion
May 17, 2016

- Roundtable discussions with:
  - DHP RDT&E program and Service research and development leadership;
  - Policy representatives from the Defense Health Agency (DHA), Office of the Assistant Secretary of Defense for Health Affairs, and Army, Navy, and Air Force;
  - Junior and senior scientists; and
  - Congressionally Directed Medical Research Programs (CDMRP) leadership.
DoD Medical Research: Historical Contributions

- DoD has a long history of providing significant contributions to health/medicine including:
  - Combat Trauma Care
  - Vaccines
  - Vector control

- However, a crisis in DoD medical research has been developing over a period of time.
Factors leading to deterioration in some aspects of DoD research processes/programs:

- Level of infrastructure support for medical research, especially human subjects research
- Laboratory funding paradigm: investigators may not be funded for research and have to compete for funds that may or may not support Service priorities; at the same time, DoD funds may be flowing to outside entities in support of those priorities
- Lack of clear research career paths; vanishing pool of senior researchers to lead programs/mentor new talent
Commanders of medical treatment facilities with a designated research mission are not evaluated on research conducted in their facility

- Lack of standardized research performance metrics
- Research “on your own time”
- Implicitly devalues research

Increasingly complex bureaucracy requiring leadership and investigators to manage competing and sometimes duplicative demands
Enacted FY15 DHP Budget

- DHP Appropriation*
  - O&M: ~$30.3 Billion
  - RDT&E: ~$1.7 Billion
    - CSI: ~$1.1 Billion
    - Core DHP RDT&E: ~$622 Million
  - Procurement: ~$308 Million

Total = ~$32.3 Billion

*Source: Defense Health Program FY 2016 Budget Estimates, Vol I-II (CSI = congressional special interest)
In response to lobbying, Congress authorized funds in 1993 to support breast cancer research within DoD, creating the “CDMRP to develop, direct, and manage an innovative agenda for breast cancer research.”

Expanded to 27 programs currently

Implements the investment of congressionally directed dollars and core (presidential budget appropriation) research dollars.


**Source: CDMRP Annual Report, 2015.
Way Ahead

- Continue monthly teleconferences/meetings
- Information gathering through mid 2016
- Military Health System Research Symposium (August 2016)
- Begin deliberation of findings and recommendations in Fall 2016
- Draft report for February 2017 DHB meeting