Public Health Subcommittee

Improving Defense Health Program Medical Research Processes

Defense Health Board February 10, 2016



Overview

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Membership

Public Health Subcommittee

- RADM (Ret.) H. Clifford Lane, MD (Chair)
- Sonia A. Alemagno, PhD
- Gary P. Carlson, PhD
- John D. Clements, PhD
- Steven M. Gordon, MD
- John D. Groopman, PhD
- David L. Lakey, MD
- James E. Lockey, MD, MS
- Gregory A. Poland, MD
- Maj (Ret.) Joseph Silva, Jr., MD





"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."

- Acting Under Secretary of Defense (Personnel & Readiness) (USD(P&R)) Memo dated September 30, 2015

(2 of 3)



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.

(3 of 3)



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.





Meetings Held

- October 29, 2015 Kickoff Teleconference
- December 17, 2015 Meeting at Uniformed Services University of the Health Sciences (USUHS)
- January 28, 2016 Teleconference

Upcoming Meetings

- March 4, 2016 Meeting at San Antonio Military Medical Center
- April to July 2016 Teleconferences



Meeting Highlights

(1 of 2)

October 29, 2015

Kickoff teleconference

December 17, 2015

- Roundtable discussions at USUHS with research leadership and senior/mid-career investigators:
 - Defense Health Agency (DHA)
 - Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA))
 - Army/Navy/Air Force representatives
 - USUHS
 - Walter Reed National Military Medical Center
 - U.S. Army Medical Research and Materiel Command



Meeting Highlights

(2 of 2)

January 28, 2016

- Roundtable discussions with institutional review board (IRB) leadership and policy representatives from the DHA, OASD(HA), and Army, Navy and Air Force
 - Work underway to harmonize processes
 - New electronic IRB system to be implemented soon
 - Looking to harmonize with revised Common Rule
 - Need to clarify process for command buy-in



Areas of Interest

- Multiple common challenges identified:
 - Restrictions on how O&M and RDT&E funds may be used complicates the ability to support complimentary efforts
 - Poor visibility on O&M funded research
 - Lack of clear research career track leads to a lack of mid- and late-career individuals
 - Affects overall quality of research
 - Compromises mentoring of new investigators



Way Ahead

- Continue monthly teleconferences/meetings
- Information gathering through mid 2016
- Begin deliberation of findings and recommendations in Summer 2016
- Draft report for February 2017 DHB meeting