



Public Health Subcommittee

Decision Brief:

Improving Defense Health Program Medical Research Processes

Defense Health Board

June 26, 2017

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Overview

- Tasking
- Membership
- Timeline
- Findings & Recommendations



Tasking

(1 of 3)

“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 [Defense Health Program] DHP medical research.”

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



Tasking

(2 of 3)

Request that the DHB address and develop findings and recommendations on the following:

- Determine how DoD may **improve visibility on DHP medical research supported through separate funding sources** (research, development, test, and evaluation (RDT&E) and operations and maintenance (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.



Tasking

(3 of 3)

Request that the DHB 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.



Public Health Subcommittee Membership

- Ten members of the Subcommittee, to include one member as the Chair



Timeline

- **October 2015:** Subcommittee begins investigation.
- **December 2015 – December 2016:** Members receive briefings and hold roundtable discussions with Department of Defense (DoD) medical research leadership; junior-, mid-, and senior-level investigators (active duty and civilian); and representatives from a non-profit foundation.
- **April 2016 – January 2017:** Members develop draft report and findings and recommendations for the Defense Health Board's (DHB's) consideration.
- **February 2017:** Presented pre-decisional draft to DHB.
- **March – April 2017:** Refined report for DHB's approval.



Defense Health Program Medical Research

For the purposes of this report and its findings and recommendations, the Subcommittee defined “DHP medical research” as:

- medical research funded by DHP or taking place at DHP-funded facilities.

FINDINGS AND RECOMMENDATIONS



Finding 1

(1 of 4)

Finding 1: The Department of Defense’s medical research enterprise is fragmented across the Services with an array of different approaches, funding streams, and goals. This is not unique to Defense Health Program medical research activities. Despite clear direction in Department of Defense Instruction 6000.08 stating that one of the objectives of Defense Health Program medical research is to “maintain a medical research portfolio that is responsive to the needs of the MHS [Military Health System] and the dynamic nature of the health sciences,” there is no comprehensive top-down strategy to ensure that this is accomplished.



Finding 1

(2 of 4)

Specifically:

- While the periodic Capabilities Based Assessments are one attempt to try to provide a comprehensive view of ongoing medical research and set priorities, this only includes research, development, test, and evaluation funding, and it is not clear how these periodic reviews have impacted priorities or how follow up takes place in the interim to assure research activities are aligned with these priorities.
- While there are annual Joint Program Committee reviews of capability gaps and *ad hoc* Armed Services Biomedical Research and Evaluation Management Community of Interest reviews, it is not clear how well these evaluations map to overall decision-making regarding approval of research activities throughout the Department of Defense.



Finding 1

(3 of 4)

Specifically (continued):

- The Defense Health Agency Research and Development Directorate, through the Joint Program Committees, plans to roll out integrated program plans for Defense Health Program research, development, test, and evaluation-funded research in 2017 aligned to validated, prioritized capability gaps. These plans do not encompass all DHP medical research (e.g., research, development, test, and evaluation and Clinical Investigation Programs and extramurally-funded research).



Finding 1

(4 of 4)

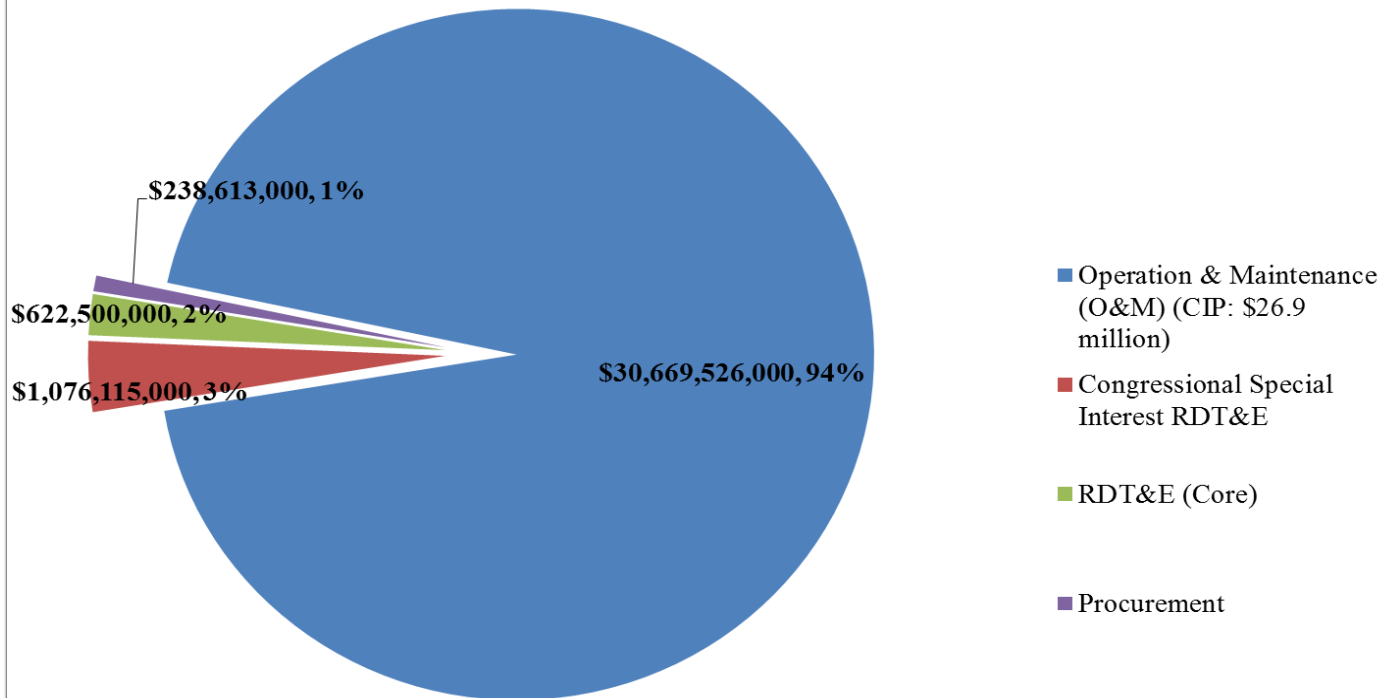
Specifically (continued):

- There is no external, independent oversight of all Defense Health Program medical research as a whole.
- Defense Health Program-funded medical research (research, development, test, and evaluation and Clinical Investigation Programs) is only a portion of all Department of Defense-conducted medical research. Visibility of all Department of Defense-conducted medical research would help facilitate the best use of Defense Health Program medical research funding to support the mission of the Military Health System.



Defense Health Program Medical Research Funding

Fiscal Year 2015 Total Enacted DHP Budget



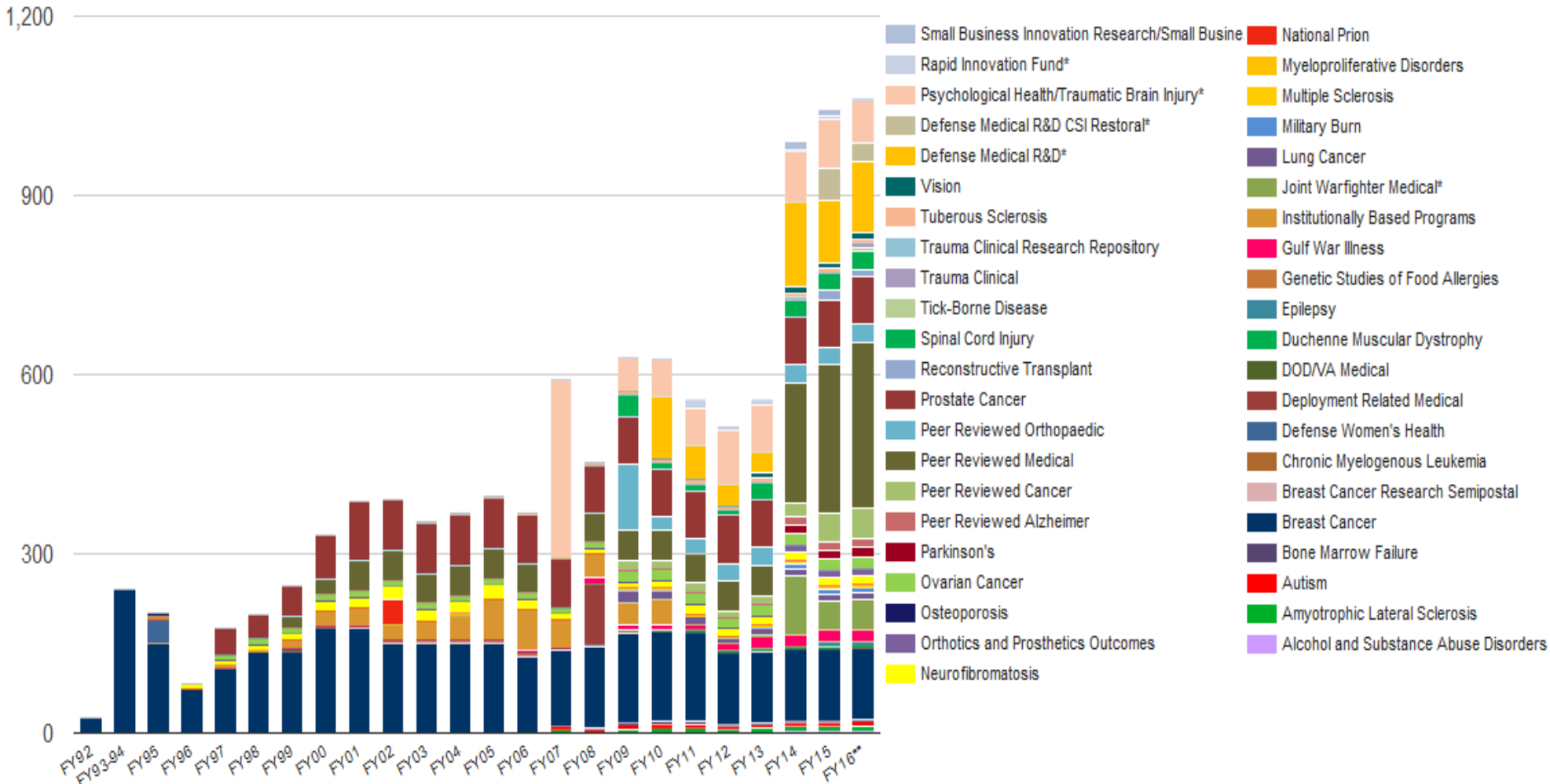
Congressional Special Interest research accounted for 63% of RDT&E funded directly by the DHP.

The Subcommittee was not able to determine the entire level of expenditure on biomedical research within the DHP.



Congressionally Directed Medical Research Programs

Congressional Appropriations

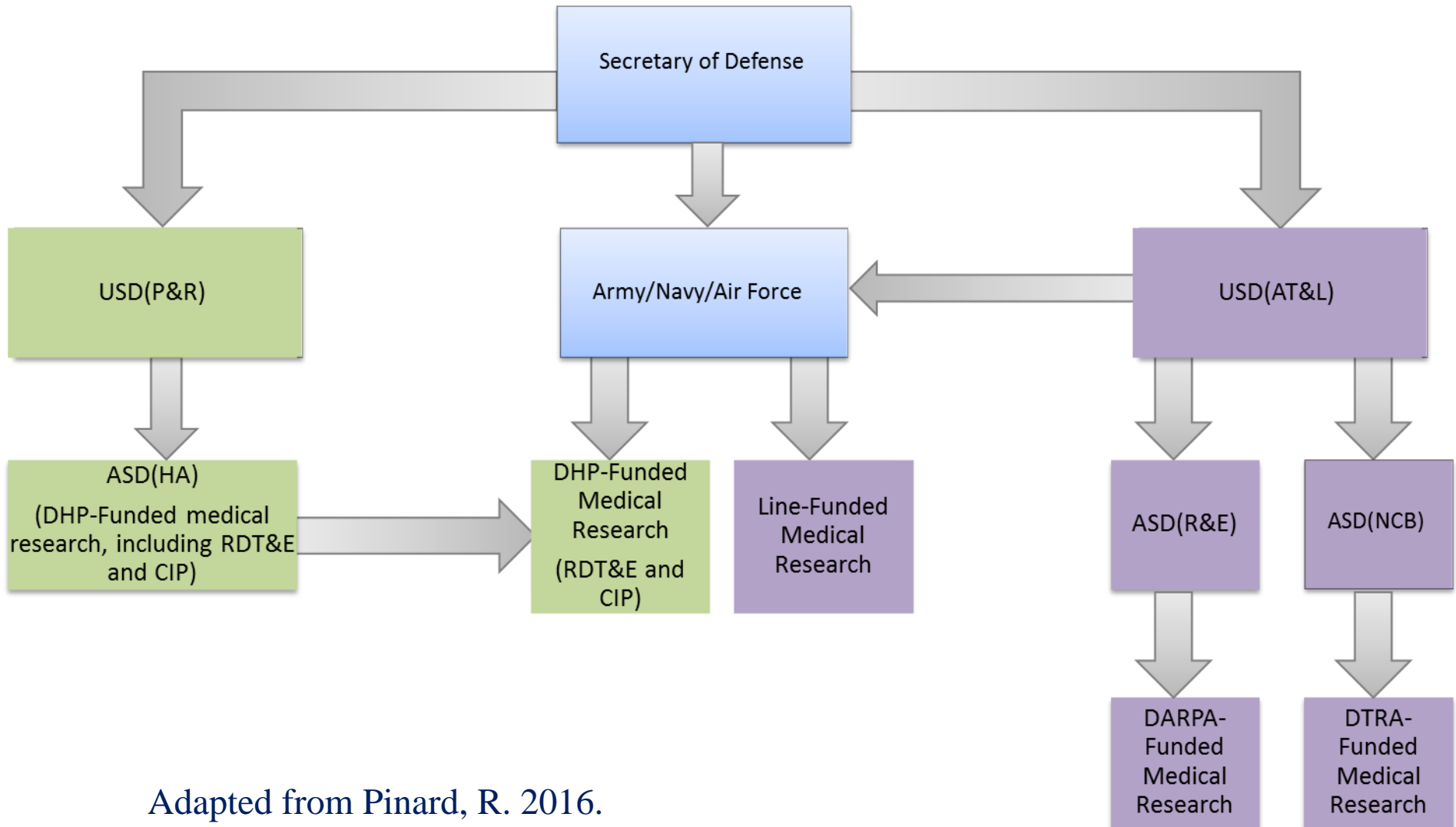


Source: <http://cdmrp.army.mil/about/fundinghistory>; Updated 1/27/2017

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DoD Medical Research

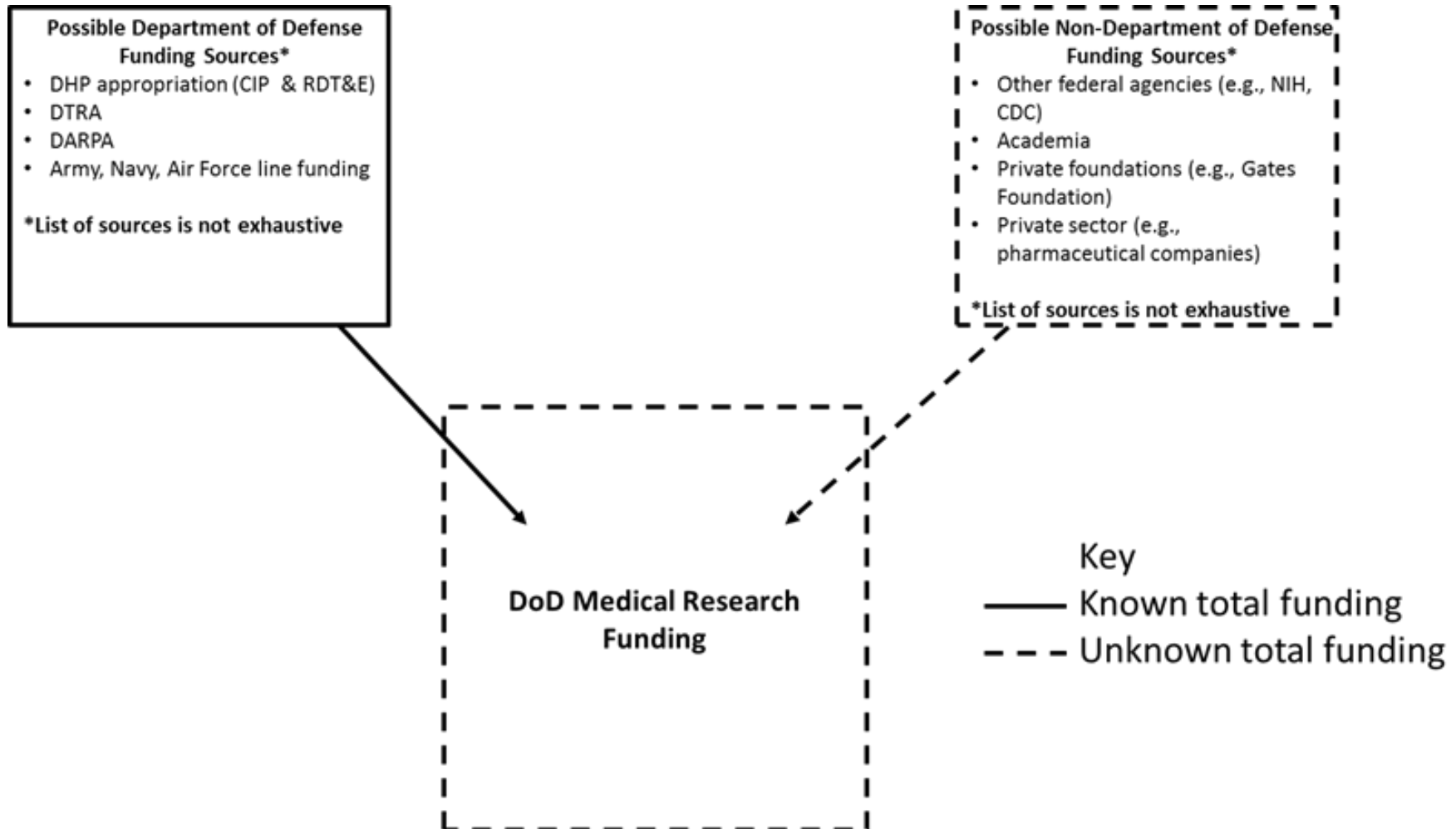


Adapted from Pinard, R. 2016.

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DoD Medical Research Funding





Recommendations 1a & 1b

Recommendation 1: The Director of the Defense Health Agency Research and Development Directorate should:

- a) have direct oversight over all Defense Health Program medical research in accordance with the spirit of the Fiscal Year 2017 National Defense Authorization Act. Specifically, the Director should be responsible for developing a strategy and operational plan for Defense Health Program medical research.
- b) issue a comprehensive biennial report on the status of Department of Defense-conducted medical research emphasizing impact on readiness and public health from the different programs across the Services. This report should be made readily available to the public.

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Recommendations 1c-1e

Recommendation 1: The Director of the Defense Health Agency Research and Development Directorate should (continued):

- c) ensure that the integrated program plans developed by the Joint Program Committees take into account all Defense Health Program medical research.
- d) conduct periodic, external scientific reviews of the Joint Program Committees' integrated program plans.
- e) ensure that all non-classified Defense Health Program research, development, test, and evaluation-funded medical research is entered into Federal RePORTER.



Recommendation 1f & 1g

Recommendation 1: The Director of the Defense Health Agency Research and Development Directorate should:

- f) ensure that all Defense Health Program medical research clinical trials conducted by or funded through the Department of Defense are listed on ClinicalTrials.gov.
- g) create a database that provides visibility of all Defense Health Program medical research. This should include but not be limited to Defense Health Program-funded research, line-funded research, other Department of Defense-funded research (e.g., Defense Threat Reduction Agency and Defense Advanced Research Projects Agency), or extramurally-funded research (e.g., other federal agencies, private industries, foundations, and academia).



Finding 2

(1 of 3)

Finding 2: Department of Defense Instruction 6000.08 requires maintenance of a medical research portfolio that is responsive to the needs of the Military Health System. The Board has identified major challenges in carrying out this requirement. Specifically:

- There is a lack of clearly defined career paths for officers skilled in medical research. This contributes to an exodus of current officers with this skill set, a shortage of mentors for junior officers with this interest, and a threat to the continuity of ongoing research.
- There is no overall strategy to recruit individuals to conduct medical research. Health professionals are recruited because of their clinical skills.



Finding 2

(2 of 3)

Specifically (continued):

- Given the primary focus of military treatment facility commanders on clinical care relative value units, there is variable and generally limited command support for medical research with investigators often taking this task on after completing required duty hours.
- While it was often stated that Defense Health Program research, development, test, and evaluation funds could not be used to support Clinical Investigation Programs research, the Board could find no such restriction and, in fact, instruction to the contrary (Department of Defense Instruction 6000.08).



Finding 2

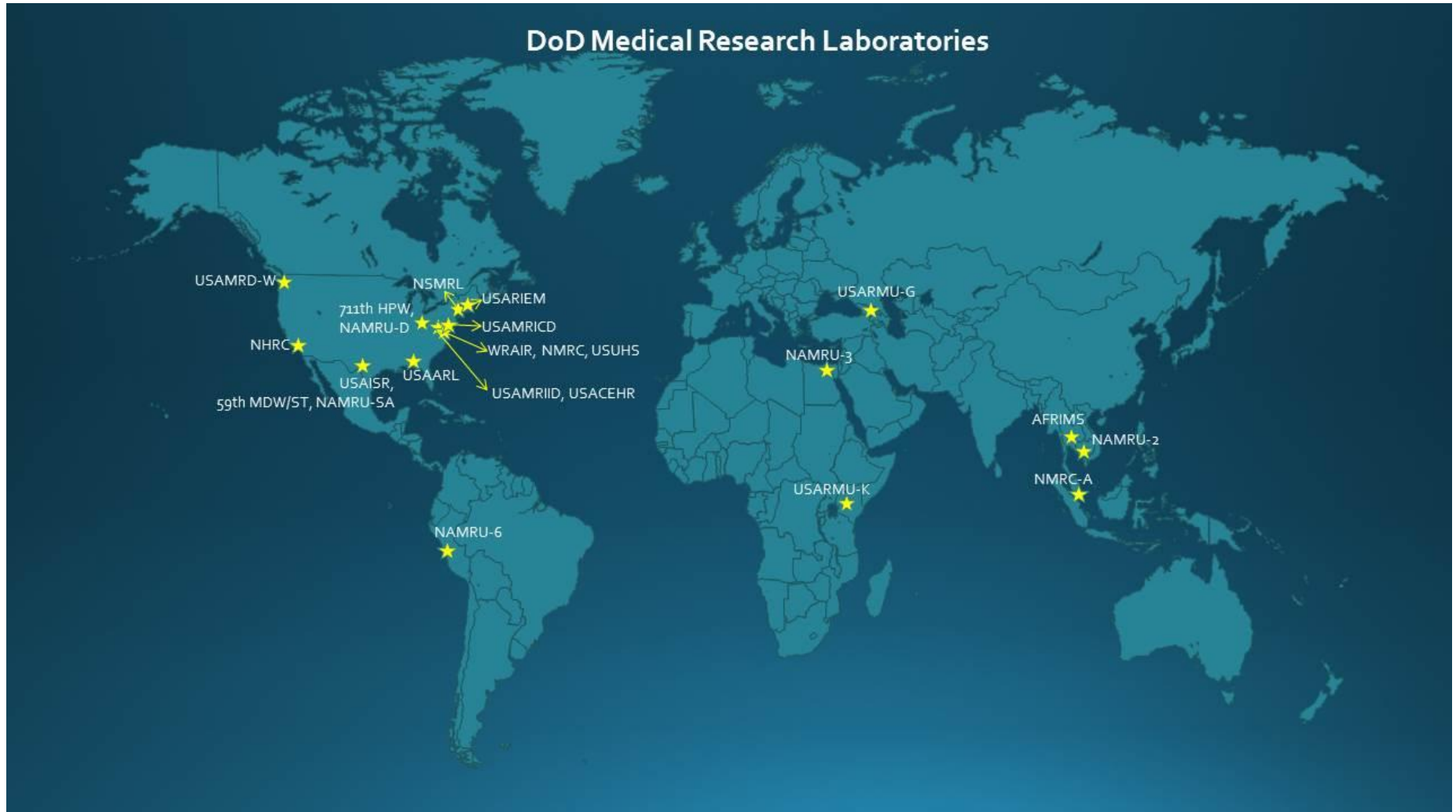
(3 of 3)

Specifically (continued):

- While Defense Health Program research, development, test, and evaluation funds are used to support the basic infrastructure for research, development, test, and evaluation laboratory facilities, such as the U.S. Army Medical Research Institute of Infectious Diseases, there are no funds directly allocated to the research in these facilities with the scientists needing to obtain additional funding for their actual research. These funds may come from the Defense Health Program or other Department of Defense or extramural sources. Accordingly, the research agenda is at risk of being driven by funding opportunities as opposed to the genuine needs of the warfighter.



DoD Medical RDT&E Laboratories

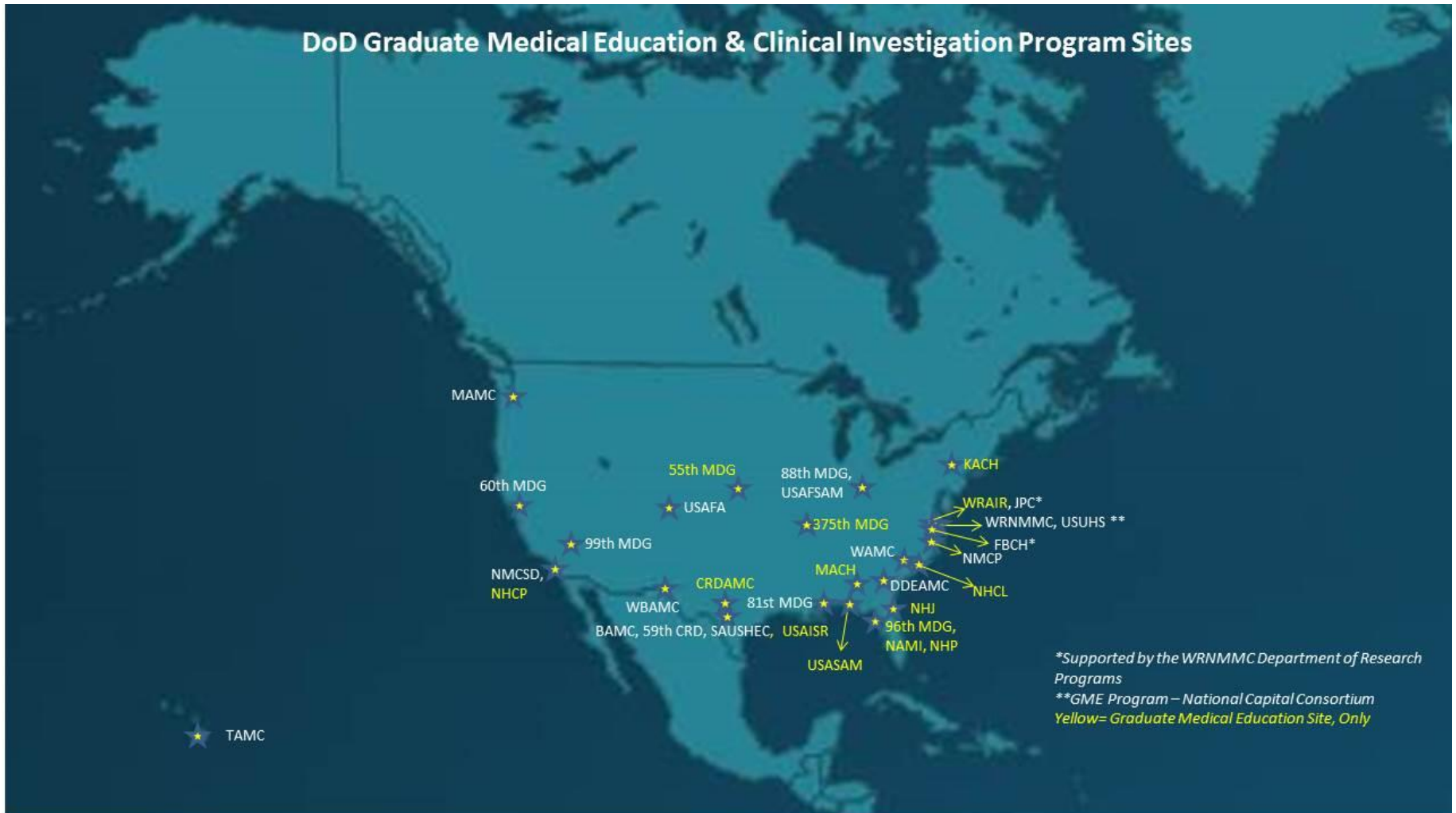


Adapted from USAMRMC, NMRC, and AFRL.

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DoD CIP and GME Sites



Adapted from information provided by DHA Education and Training; Army, Navy, Air Force CIP leadership.

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Recommendation 2a

Recommendation 2: The Department of Defense should increase support for medical research as a clear mission of the Military Health System. Specifically:

- a) The Services should develop a clear recruitment strategy and career and leadership paths for officers with an interest in medical research. Appropriate education, training, and opportunities to develop expertise in medical research should be provided. This should include the potential for eventual command opportunities at the medical research, development, test, and evaluation facilities. As in all such efforts, there should be a focus on equal opportunity and the development of a diverse research workforce.



Recommendation 2b

Recommendation 2: The Department of Defense should increase support for medical research as a clear mission of the Military Health System. Specifically (continued):

- b) The Services should include in the performance evaluation of military treatment facility commanders, and by extension their Department Heads, an evaluation of the research carried out in their military treatment facilities and Departments. This evaluation should include the impact of the research **on the genuine needs of the warfighter**, readiness, the public health impact, and the number/quality of publications/presentations.



Recommendations 2c & 2d

Recommendation 2: The Department of Defense should increase support for medical research as a clear mission of the Military Health System. Specifically (continued):

- c) The Military Health System should establish a relative value unit for medical research at the military treatment facilities or prorate the number of relative value units required for individuals who also conduct research.
- d) The Services should use Defense Health Program research, development, test, and evaluation funds across the Department of Defense medical research enterprise to support medical research at the military treatment facilities and to support a core amount of research at the research, development, test, and evaluation facilities.



Finding 3

(1 of 2)

Finding 3: The Department of Defense’s current approach and support for medical research have not kept pace with the vast changes that have taken place in the practice of medical research, and, as such, the infrastructure support (administrative, scientific, and technical) for medical research in general, and human subjects research at the military treatment facilities in particular, is seriously inadequate. Specifically:

- These shortcomings have been recognized repeatedly over the years without being adequately addressed; one cannot conduct high-quality research safely without this type of support.



Finding 3

(2 of 2)

Specifically (continued):

- Currently, there is a lack of standardization, varying levels of expertise at technology transfer programs across the Services, and limited intellectual property support for Defense Health Agency inventions. This leads to system-wide barriers in internal collaborations and extramural partnerships.



Examples of Research Support

Category	Position/Title	
Administrative Support	<ul style="list-style-type: none"> • Biobank Manager • Budget Analyst • Clinical Data Entry Clerk 	<ul style="list-style-type: none"> • Database Manager • Grants Writer • Technical Writer
Scientific/Technical Support	<ul style="list-style-type: none"> • Bioinformatics Analyst • Biologist • Biostatistician • Chemist • Clinical Protocol Developer • Clinical Research Coordinator 	<ul style="list-style-type: none"> • Clinical Research Nurse • Clinical Trials Auditor • Clinical Trials Coordinator • Laboratory Technician • Research Assistant • Veterinary Technician



Recommendations 3a & 3b

Recommendation 3: The Defense Health Agency should:

- a) establish several regional, tri-Service research infrastructure support centers. The centers should be available to all Defense Health Program investigators within their designated region and provide the necessary infrastructure and oversight (e.g., those shown in Table 3 of Appendix C.6) to ensure high-quality, regulatory compliant, and safe research.
- b) implement a harmonized technology transfer program in accordance with Department of Defense policy.



Findings 4a & 4b

Finding 4a: The Institutional Review Board process is currently fragmented across the Services with different protocol templates, requirements, and methods of implementation. The current move to a uniform electronic Institutional Review Board system is a significant step forward, but it does not address the lack of consistency across the Services. The recent revision to 45 Code of Federal Regulations part 46 (the “Common Rule”) strongly encourages use of a single Institutional Review Board for multi-center studies.

Finding 4b: Protocols submitted to the Institutional Review Board are at times in need of significant revision from the scientific as well as the human subjects protections perspective.



Recommendations 4a & 4b

Recommendation 4: The Defense Health Agency should:

- a) designate the Director of the Defense Health Agency Research and Development Directorate as the single Institutional Official for all of the Department of Defense human subjects research to provide uniform oversight for all Department of Defense Institutional Review Boards.
- b) consolidate Institutional Review Board functions at the regional, tri-Service research infrastructure support centers envisioned in Recommendation 3a and ensure that they receive the adequate resources to carry out their role.



Recommendations 4c & 4d

Recommendation 4: The Defense Health Agency should
(continued):

- c) establish policies and procedures to require a single Institutional Review Board to serve as the Institutional Review Board of record for multi-center studies. These Institutional Review Boards should be located at the regional, tri-Service research infrastructure support centers envisioned in Recommendation 3a.
- d) instruct the Institutional Official to establish standardized metrics of performance for Department of Defense Institutional Review Boards and ensure compliance to those metrics.



Recommendation 4e

Recommendation 4: The Defense Health Agency should
(continued):

- e) ensure that each protocol undergoes a review and approval by the relevant Department prior to Institutional Review Board submission to ensure the study is mission relevant, scientifically rigorous, and ethically sound.



Finding 5

Finding 5: The essential elements of cost-effective research include clear command support for medical research, adequately trained personnel, adequate infrastructure support, and core funding. However, these are not consistently present throughout the Defense Health Program medical research enterprise. Given the lack of adequate core funding for research infrastructure and lack of career opportunities, medical research is not seen as an attractive career option. In addition, the pay scales for civilian medical researchers are not comparable to either the private sector or other governmental agencies.



Recommendations 5a-5c

Recommendation 5: The Department of Defense must:

- a) provide the necessary research infrastructure support and core funding to conduct research and instruct the Military Health System commands to embrace medical research as an essential part of their mission.
- b) view medical research as an active duty career track and competency with special pays for research analogous to other specialty fields.
- c) pursue the appropriate authority to incorporate the civilian pay scales present in other federal agencies through Titles 38 and 42 to provide adequate pay incentives for Department of Defense civilian health professionals engaged in military medical research.



Finding 6

(1 of 2)

Finding 6: The Department of Defense has an extraordinary history of accomplishments in medical research including confirmation of routes of transmission of infectious diseases, development of vaccines, and enhanced combat casualty care. However, the majority of the public is unaware of this history and ongoing efforts. There are a series of meetings that could facilitate communication of Defense Health Program medical research successes and recruit Department of Defense investigators.



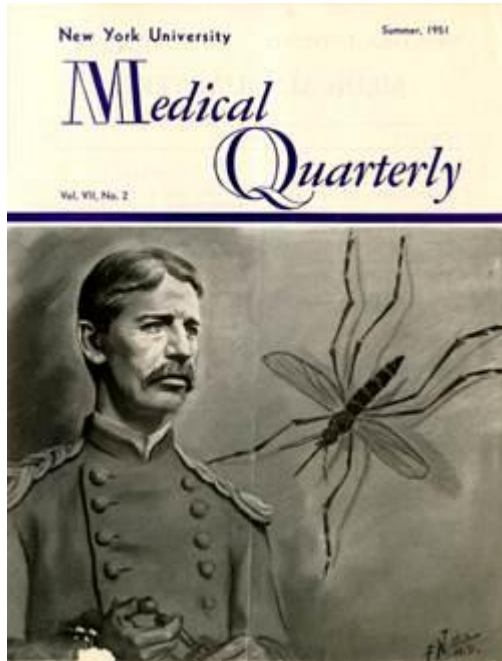
Finding 6

(2 of 2)

Finding 6 (continued): These include Department of Defense meetings, such as the Military Health System Research Symposium, as well as other scientific and professional meetings. However, recent conference attendance restrictions have impeded the ability for investigators to attend these meetings, present their findings, and network with colleagues. In addition, not all completed research studies make their way to peer-review publication.



DoD Medical Research: Historical Contributions



Vector Control
(e.g., Typhoid
Fever and Yellow
Fever)



**Combat Casualty
Care**
(e.g., tourniquets, blood
products)



Vaccines
(e.g., Japanese
encephalitis)



DoD Medical Research: Recent Efforts



Battlefield Health and Trauma Center for Human Integrative Physiology

(e.g., lower body negative pressure model to study physiology of human hemorrhage)



Vector-Borne Disease Research (e.g., Zika and Middle East Respiratory Syndrome)

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Recommendations 6a & 6b

Recommendation 6: The Department of Defense should:

- a) ensure broad distribution of the biennial report discussed in Recommendation 1b.
- b) ensure that the annual Military Health System Research Symposium contains a section highlighting accomplishments of the past year and perhaps a review of a key medical research area to facilitate recognition across the Department of Defense of medical research successes and contributions and do this in concert with appropriate press briefings.



Recommendations 6c & 6d

Recommendation 6: The Department of Defense should:

- c) allow, encourage, and fund investigators to present their findings at national and international specialty and subspecialty meetings.
- d) indicate that investigators are expected to publish their findings in national, peer-reviewed journals in a timely manner, with appropriate acknowledgment of Department of Defense funding.



Questions?