



# Improving Defense Health Program Medical Research Processes

A Report by the Defense Health Board

August 8, 2017

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DEFENSE  
HEALTH  
BOARD

**OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE  
HEALTH AFFAIRS**

7700 ARLINGTON BOULEVARD, SUITE 5101  
FALLS CHURCH, VA 22042-5101

August 8, 2017

**MEMORANDUM FOR PERFORMING THE DUTIES OF THE ASSISTANT SECRETARY  
OF DEFENSE FOR HEALTH AFFAIRS**

**SUBJECT: Improving Defense Health Program Medical Research Processes**

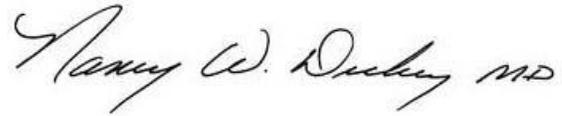
The Defense Health Board (DHB) is pleased to submit its report summarizing the findings and recommendations from its independent review of Improving Defense Health Program (DHP) Medical Research Processes.

On September 30, 2015, the Acting Under Secretary of Defense for Personnel and Readiness (USD(P&R)) tasked the DHB to provide recommendations regarding approaches that would optimally support military medical professionals who oversee and conduct DHP medical research. In response, the DHB assigned the Public Health Subcommittee to examine the processes for conducting DHP medical research and Clinical Investigation Programs in the Department of Defense (DoD). It was requested that the Subcommittee provide recommendations on the following:

- Determine how DoD may improve visibility on DHP medical research supported through separate funding sources (research, development, test, and evaluation and operations and maintenance) to enhance coordination of effort, oversight, and collaboration;
- Determine the major challenges that DoD investigators face in initiating, funding, attaining approval, 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;
- 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 research; and
- 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.

The Subcommittee conducted an in-depth literature review; received briefings from subject matter experts; and conducted panel discussions with DHP medical research policy leaders, as well as civilian and active duty investigators at the junior, mid, and senior-levels. Following public deliberation of the findings and recommendations, the attached report was finalized.

On behalf of the DHB, I appreciate the opportunity to provide the Department with this independent review and hope that it provides useful information to enhance the initiation and conduct of medical research across the enterprise.

A handwritten signature in black ink that reads "Nancy W. Dickey MD". The signature is written in a cursive, flowing style.

Nancy W. Dickey, MD, FAAFP  
President, Defense Health Board

Attachment:  
As stated



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## IMPROVING DEFENSE HEALTH PROGRAM MEDICAL RESEARCH PROCESSES

*“Research enhances the vitality of teaching; teaching lifts the standards of service; and service opens new avenues of investigation.”*

Dr. Jack Masur  
Director of the National Institutes of Health Clinical  
Center, 1948-1951 & 1956-1969

The Department of Defense’s (DoD’s) medical mission is to “enhance DoD and our Nation’s security by providing health support for the full range of military operations and sustaining the health of all those entrusted to our care.”<sup>1</sup> The Military Health System (MHS), one of the Nation’s largest and most complex health care systems, carries out this medical mission. The MHS is a unique network of health professionals providing health care delivery services to approximately 9.4 million beneficiaries, including Service members, dependents, and retirees.<sup>2</sup> The MHS also performs other activities, such as medical education, public health services, and medical research and development,<sup>3</sup> which are critical for enhancing the proficiency of its providers, maintaining the health of its beneficiaries, and advancing the science of health care.

Medical research fosters improvements in the practice of medicine and overall population health.<sup>4</sup> DoD’s medical researchers have contributed a number of significant advancements to the field, including U.S. Army physician Walter Reed and his team’s discovery and confirmation of the transmission of deadly diseases such as typhoid fever and yellow fever.<sup>5</sup> Researchers also contributed to the development of intravenous therapy for cholera;<sup>6</sup> and the development of anti-malarial agents such as chloroquine, doxycycline, and atovaquone-proguanil at the Walter Reed Army Institute of Research.<sup>7</sup> Recent examples of DoD’s contributions to medical research include combat casualty care research advances, such as the use of hemostatic dressings and re-introduction of tourniquets during Operation IRAQI FREEDOM and Operation ENDURING FREEDOM,<sup>8</sup> which have led to a reduction in combat trauma case fatality rates and are already influencing civilian trauma practices.<sup>9</sup> DoD has also demonstrated public health leadership in responding to the West Africa Ebola outbreak by developing the clinical assays “now considered the gold standard for Ebola detection tools,”<sup>10</sup> surveillance test kits, and vaccines.<sup>10</sup> As such, research is integral to creating a “medically ready force” as well as a “ready medical force.”

DoD also performs medical research aimed at improving the health of all MHS beneficiaries, not just its warfighters, such as research conducted under the Congressionally Directed Medical Research Programs (CDMRP).<sup>11</sup> The CDMRP has 28 research focus areas including breast, prostate, and ovarian cancer programs.<sup>12</sup> The Department also conducts and sponsors medical research at civilian research institutions<sup>13</sup> and frequently collaborates with foreign Ministries of Health and the World Health Organization to advance global health.<sup>14</sup> DoD medical research has also provided valuable guidance for civilian policy and practices. For example, DoD’s HIV cohort informed the Social Security Administration’s policy for HIV disability ratings.<sup>15</sup>

DoD is one of the largest federal medical research institutions in the United States<sup>16</sup> with diverse venues for conducting research, including military treatment facilities (MTFs), such as Walter



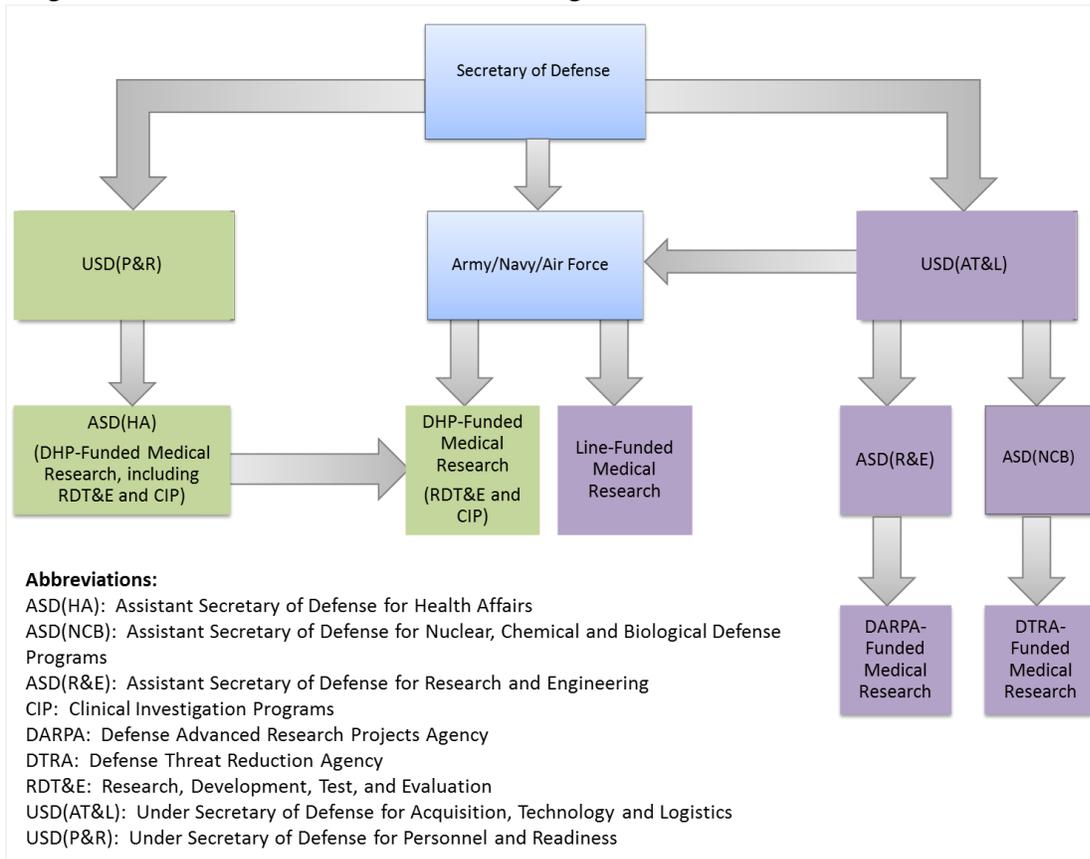
Reed National Military Medical Center (WRNMMC); medical research laboratories, such as the U.S. Army Medical Research Institute of Infectious Diseases and its Biosafety Level-4 laboratory; and the Uniformed Services University of the Health Sciences. Within DoD, various agencies conduct and sponsor medical research, such as agencies under the authority of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) or the Under Secretary of Defense for Acquisition, Technology and Logistics (Figure 1a). DoD had a medical research portfolio of more than \$1.7 billion\* in Fiscal Year (FY) 2015 alone; Figure 1a illustrates the basic chains of authority for the \$1.7 billion in Defense Health Program (DHP) medical research funding, which is only a portion of the total DHP medical research budget. The Defense Health Board (DHB) was unable to ascertain total DHP medical research funding from DoD and extramural sources. Medical research may also be funded by the Army, Navy, or Air Force (e.g., line-funded), or research may be funded through non-DoD sources, such as private industry, National Institutes of Health (NIH), Centers for Disease Control and Prevention, private foundations, and others (Figure 1b). These disparate funding sources may fund research that is not primary to the needs of the DoD and lead to opportunity costs, diverted resources (e.g., research personnel and infrastructure), and may compromise the primary mission of DHP medical research.

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\*This amount is the total DHP research, development, test, and evaluation (\$1.7 billion in Congressional Special Interest and core funding, combined) and Clinical Investigations Program (\$26.9 million intramural DHP operations and maintenance funding) for Fiscal Year 2015. This does not include non-DoD extramural funds.

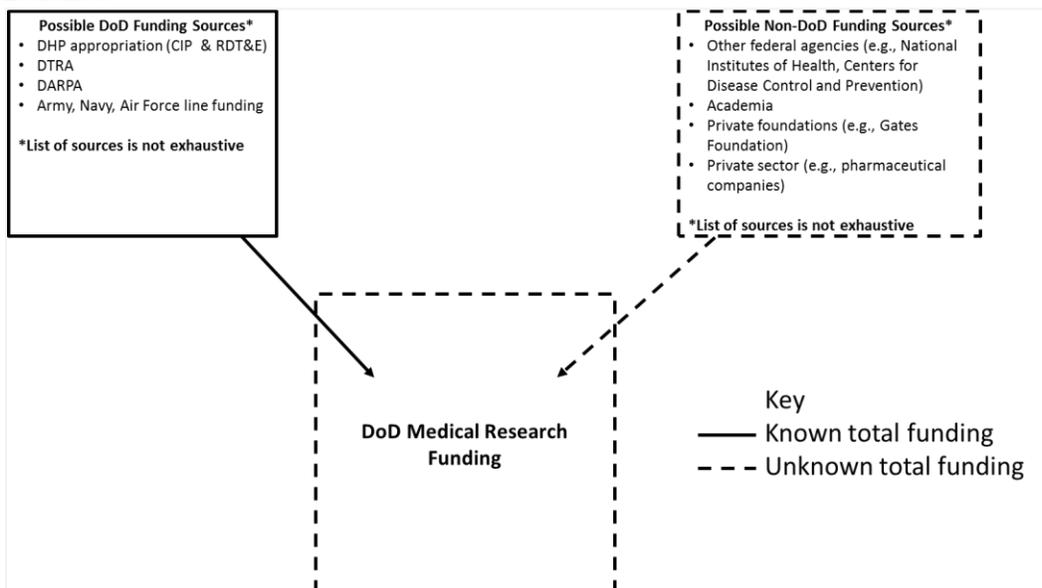


**Figure 1a.** Basic Chains of Authority and Oversight for Defense Health Program and Line Medical Research Funding.<sup>17</sup>



Adapted from R. Pinard, 2016.

**Figure 1b.** Possible Sources of Funding for Medical Research Conducted in the Department of Defense.





As defined by the DoD Instruction (DoDI) 6000.08, *Defense Health Program Research and Clinical Investigation Programs*, research is “any systematic study directed toward fuller scientific knowledge or understanding of military healthcare and in support of health readiness solutions that protect, treat, and optimize the health and performance of the total force.”<sup>18</sup> However, DoDI 6000.08 does not explicitly define “medical research.” For the purposes of this report, the DHB uses the term “medical research” to be inclusive of non-human subjects research (e.g., basic, *in vitro*, and laboratory research) and human subjects research relating to the medical mission of the MHS. Further, the DHB defines “DHP medical research” as medical research funded by DHP or taking place at DHP-funded facilities.

## 1.1 HISTORY OF THE DEFENSE HEALTH PROGRAM AND BACKGROUND

Historically, each of the Military Departments (the Services, or Army, Navy, and Air Force) funded its respective health care operations using its own appropriations.<sup>19</sup> However, as health care costs increased nationwide and within DoD, a larger portion of the Department’s budget was consumed by health care expenditures. In order to curb these increasing health care costs and increase visibility of health care expenditures, the Deputy Secretary of Defense signed a Program Budget Decision in 1991 creating the DHP appropriation.<sup>19</sup>

As mandated by the Program Budget Decision, the Services parsed out what they had historically spent on medical care and resources and transferred those amounts from their respective operations and maintenance (O&M); research, development, test, and evaluation (RDT&E); and procurement appropriations into the new unified DHP appropriation.<sup>19</sup> Each Service then determined how much funding to transfer to the DHP and how to restructure itself organizationally to manage its respective DHP allocations. The Army and Navy established medical commands (U.S. Army Medical Command and U.S. Navy Bureau of Medicine and Surgery). The Air Force did not restructure itself organizationally and only transferred to DHP the funds needed to operate the MTFs; the Air Force Medical Service only receives DHP funds “to pay for commodities consumed within the walls of Air Force MTFs.”<sup>19</sup>

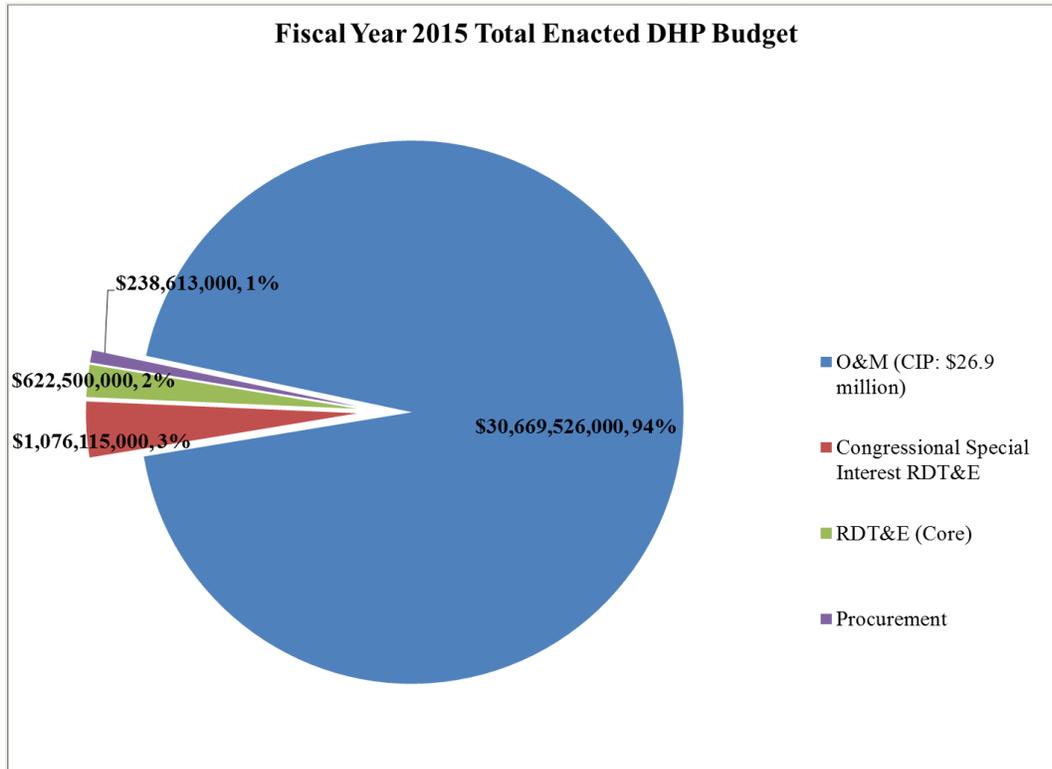
As specified in DoDI 6000.08, “DHP-funded medical research and CIP [Clinical Investigation Programs] are essential missions of the MHS.”<sup>18</sup> The primary objectives of DHP medical research and CIPs include optimizing the health and performance of the total force; improving the quality of patient care in the MHS through improved knowledge, practices, materiel, pharmaceuticals, and evidence-based treatment and guidelines; and maintaining a medical research portfolio responsive to the needs of the MHS.<sup>18</sup> The total DHP budget (RDT&E, O&M, and Procurement) has increased substantially over the past 15 years, from \$13.7 billion enacted in FY 2001<sup>20</sup> to more than \$32 billion enacted in FY 2015.<sup>1</sup> Of the \$32 billion enacted in FY 2015, medical research was 5 percent of the budget. Of note, over 60 percent of the medical research budget was devoted to Congressional Special Interest research (Figure 2), which may or may not be immediately applicable to the warfighter.

The DHP O&M funds support “the delivery of health care in the military treatment facilities and private sector and associated operating activities, education, base operating support, and management oversight, including infrastructure management of [clinical investigations].”<sup>18</sup> DHP O&M funds also support CIPs. In FY 2015, the total budget for CIPs was \$26.9 million, which



comprised less than 0.1 percent of the DHP O&M budget (Figure 2); the majority of DHP O&M funds are used for patient care. DHP RDT&E funds support “medical information management/information technology, medical research to reduce capability gaps, support to medical laboratory facilities inside and outside the continental United States, and the Armed Forces Radiological Research Institute.”<sup>18</sup> The total DHP RDT&E budget for FY 2015 was \$1.7 billion (Figure 2). DHP medical research oversight, processes, and opportunities for improvement will be discussed in further detail in [Section 1.4](#).

**Figure 2.** Fiscal Year 2015 Total Enacted DHP Budget<sup>1</sup>



From U.S. Department of Defense, 2015.

## 1.2 REQUEST TO THE DEFENSE HEALTH BOARD

On September 30, 2015, the Acting USD(P&R) requested that the DHB, through the Public Health Subcommittee, “provide recommendations to the Department regarding approaches that would optimally support military medical professionals who oversee and conduct DHP medical research.”<sup>21</sup> Specifically, the Acting USD(P&R) requested that the DHB:

- determine how DoD may improve visibility on 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, attaining approval, 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;



- determine how DoD may improve Institutional Review Board (IRB) processes to facilitate more efficient approval of multicenter studies and clinical trials;
- determine cost-effective mechanisms to encourage more professionals to become engaged in research; and
- 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.<sup>21</sup>

The Public Health Subcommittee of the DHB conducted an extensive literature review, received briefings, and conducted panel discussions with senior and junior investigators and with subject matter experts to address the questions outlined in the Terms of Reference ([Appendix G](#)). The Guiding Principles (Figure 3) were adopted as a foundation for the Subcommittee.

**Figure 3.** Guiding Principles

***Overarching Principle:***

DoD has a duty to conduct comprehensive medical research to provide continuous advancements in health care to support the military unique needs of the warfighter while also improving care for the entire MHS beneficiary population.

***Guiding Principles:***

These principles require that the changes recommended by the Subcommittee, when taken as a whole, must:

- i. reflect best practices in other federal research institutions, academia, and the private sector to improve the support, management, and execution of DHP medical research;
- ii. streamline the DHP (RDT&E and CIP) medical research processes to support more timely approval and efficient conduct of research, especially in the joint environment;
- iii. advocate for processes that are value added and promote safety, efficiency, mission relevance, scientific merit, collaboration, and visibility; and advocate elimination of those that do not;
- iv. take into consideration current DoD initiatives, undertakings, future plans, and medical readiness requirements of the MHS;
- v. identify opportunities to enhance the professional development of DoD medical researchers and thereby improve recruitment, promotion, and retention of talented personnel; and
- vi. improve recognition of DoD’s contribution to the medical research community.



In this report, the DHB highlights five areas that answer the six objectives posed by the USD(P&R):

- 1) The strategic role of medical research in DoD ([Section 1.3](#) and further described in [Appendix A](#));
- 2) DHP medical research oversight and execution ([Section 1.4](#) and [Appendix B](#));
- 3) Infrastructure for DHP medical research ([Section 1.5](#) and [Appendix C](#));
- 4) Professional development of DoD investigators ([Section 1.6](#) and [Appendix D](#)); and
- 5) Attribution of DHP medical research ([Section 1.7](#) and [Appendix E](#)).

The report concludes with its findings and recommendations ([Section 1.8](#)), followed by additional, supporting appendices.

### 1.3 STRATEGIC ROLE OF MEDICAL RESEARCH IN THE DEPARTMENT OF DEFENSE

DoD's medical researchers have contributed a number of significant advancements to the field that benefit not only the warfighter, but DoD beneficiaries and civilian populations as well.<sup>22</sup> Medical research discoveries are carried out in diverse settings throughout DoD, including medical research facilities such as the U.S. Army Medical Research Institute of Infectious Diseases, Naval Medical Research Center, the Air Force Research Laboratory, the Uniformed Services University of the Health Sciences (USUHS), and at individual bases within the MHS (primarily through DHP O&M-funded CIPs). DHP-supported research is also performed extramurally at academic institutions and in industry with financial support from DoD.

#### ROLE OF COMMAND

It is DoD policy that "DHP-funded medical research and CIP are essential missions of the MHS,"<sup>18</sup> intended to achieve the following objectives: 1) develop and employ health readiness solutions that protect, treat, and optimize the health and performance of the total force; 2) improve the quality of patient care in the MHS by improving medical knowledge, practice, material, devices, pharmaceuticals, and by providing the DoD beneficiary population with access to evidence-based diagnosis and treatment; and 3) maintain a medical research portfolio that is responsive to the needs of the MHS and the dynamic nature of the health sciences.<sup>18</sup> This requires that DoD's health-related leadership across the Department, Services, the Defense Health Agency (DHA), and commanders at every level make basic, clinical, and translational research a priority. However, despite being indicated as "essential missions of the MHS,"<sup>18</sup> there was consistent concern about insufficient command attention to the conduct of research during roundtable discussions with DoD investigators and DHP medical research leadership.

#### SETTING THE DEFENSE HEALTH PROGRAM MEDICAL RESEARCH AGENDA: ROLES AND RESPONSIBILITIES

In addition to the multiple sources and levels of strategic guidance concerning DHP medical research, the Department has disparate mechanisms for directing, coordinating, resourcing, and overseeing research activities. Also, the Services have their own policies and programs for conducting and supporting research.<sup>57,74-77</sup> The recently passed National Defense Authorization Act (NDAA) for FY 2017 will soon direct an evolution in the roles and responsibilities for the



DHA and the MTFs, in particular.<sup>23</sup> The DHB took this into account as its findings and recommendations were developed.

There are numerous entities involved in developing the requirements and strategic guidance for DoD and DHP medical research. These include:

- The **Assistant Secretary of Defense for Health Affairs (ASD(HA))** who develops and issues strategic guidance in coordination with the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)) in regard to military medical research.<sup>18</sup> Capabilities Based Assessments are periodically conducted on behalf of the Office of the ASD(HA) to reassess or determine medical research capability gaps. The interval for the assessments is unclear.
- The **Director of the DHA**, who supports the conduct of studies and research activities to assist the ASD(HA) and others, as necessary, in support of their responsibilities and to support the management and implementation of health policies for the MHS developed by the ASD(HA).<sup>24</sup> Additionally, the Director exercises management responsibility for shared services, functions, and activities in the MHS, including medical research and development, as determined by the ASD(HA).<sup>24</sup>
- The **Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight**, who provides policy direction for execution management of the DHP RDT&E appropriation on behalf of the ASD(HA) and the DHA Director, including developing DHP RDT&E priorities for the fiscal year.<sup>25</sup>
- The **Joint Program Committees (JPCs)**, which are DHA Research and Development Directorate advisory bodies composed of medical and military experts that support the DHA Research and Development Director in the planning, programming, budgeting, and execution of DHP RDT&E research for specific medical research task areas.<sup>26-31</sup> The JPCs also advise U.S. Army Medical Research and Materiel Command's (USAMRMC) Program Area Directorates, which provide strategic oversight of DHA Research and Development-funded research.<sup>11</sup>
- The **CDMRP**, which works with USAMRMC's Program Area Directorates to execute a number of programs. This combined effort leverages the CDMRP's expertise in research program administration with the Program Area Directorates' technical and strategic expertise for the advancement of the DHA Research and Development mission.<sup>11</sup>
- The **Armed Services Biomedical Research Evaluation and Management Community of Interest**, established by the ASD(R&E) and co-chaired by the ASD(HA), which facilitates coordination and prevents unnecessary duplication of effort within DoD biomedical research and development and associated enabling research areas.<sup>32</sup> The Armed Services Biomedical Research Evaluation and Management Community of Interest does not set research priorities.

## CHALLENGES FOR DEFENSE HEALTH PROGRAM MEDICAL RESEARCH PRIORITIZATION

Although there are ongoing efforts to increase data sharing of DHP RDT&E research activities ([Appendix C.4](#)), the DHB frequently heard from DoD investigators that it is difficult to locate a comprehensive summary of current medical research priorities, strategic guidance, or current



activities.<sup>33</sup> Further, there is no searchable, public database<sup>†</sup> of ongoing DHP medical research, such as the NIH's ClinicalTrials.gov,<sup>35</sup> regardless of the source of funding. Additionally, there are multiple drivers of strategic guidance and requirements for DoD and DHP medical research, such as Capabilities Based Assessments; research priorities determined by the Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight<sup>25</sup> and the JPCs;<sup>26-31</sup> research initiatives directed by the White House;<sup>25</sup> as well as Service Secretaries, Surgeons General, and Combatant Command priorities.<sup>36</sup> Finally, DoD institutions, including DHP medical research laboratories and MTFs, also provide mission and vision statements, some of which do not include research. Further, research conducted at DoD RDT&E laboratories under the Chemical and Biological Defense Program may have additional drivers of requirements.<sup>37</sup> Therefore, DHP medical research has many sources of strategic guidance that may not align.

For the CIPs that support Graduate Health Sciences Education, it is unclear to what extent research priorities are made available or used by DoD investigators, including those conducting clinical investigations as part of their Accreditation Council for Graduate Medical Education (ACGME) scholarly activity requirements.

To address these challenges, there are numerous efforts to improve strategic guidance and prioritization of DHP medical research, such as the Army's Clinical and Translational Research Program Office, which will work to ensure alignment of the Army CIP portfolio with the objectives of the DHP as denoted in DoDI 6000.08.<sup>38</sup> Also, the DHA Research and Development Directorate will begin rolling out integrated program plans in 2017 to improve alignment of DHP RDT&E research funding to capability gaps.<sup>39</sup> While these distinct initiatives are beneficial, it is essential that DoD take a systematic, enterprise-wide review of its medical research activities and policies in order to develop a more coordinated and transparent strategy and operational plan to advance its medical research agenda going forward.

Additional information on challenges for DHP medical research prioritization can be found in [Appendix A](#).

## 1.4 DEFENSE HEALTH PROGRAM MEDICAL RESEARCH OVERSIGHT AND EXECUTION

Per DoD policy, the ASD(HA) "exercises authority, direction, and control over DHP research and CIP,"<sup>18</sup> and the DHA manages and executes the DHP appropriation as directed by the ASD(HA).<sup>18</sup>

### DEFENSE HEALTH PROGRAM RESEARCH, DEVELOPMENT, TEST, AND EVALUATION PROGRAM

DHP RDT&E program funding consists of core funding from the DHP RDT&E appropriation and Congressional Special Interest funding. DHP RDT&E funds are designated by budget activities 6.1-6.7,<sup>40</sup> are available for the obligation of two fiscal years, and support intramural

<sup>†</sup> A database is "a set of data that has a regular structure and that is organized in such a way that a computer can easily find the desired information."<sup>34</sup>



and extramural research.<sup>41</sup> Intramural research includes research conducted at MTFs, DoD laboratories, as well as collaborative projects. Extramural research can be conducted by other federal agencies, academia, or industry.<sup>41</sup>

Management, execution, and support of the DHP RDT&E program are complex. Within the DHA, the Research and Development Directorate manages and executes the DHP RDT&E appropriation.<sup>42</sup> The Director of the DHA Research and Development Directorate also serves as the Deputy Director of USAMRMC. Currently the Directorate does not have full financial visibility of these funds because of a lack of financial reporting below task areas (e.g., combat casualty care), inaccurate accounting mechanisms, and delays in reporting.<sup>39</sup> However, the DHA Research and Development Directorate is coordinating with the Services to create work breakdown structures within their official cost accounting mechanisms and generate automatic, quarterly reports of DHP RDT&E obligations and expenditures.<sup>39</sup>

Under USAMRMC, the CDMRP provides DHP RDT&E program execution management support for six core research program areas, each managed by a JPC.<sup>42</sup> The CDMRP, in partnership with the JPCs, supports development of program announcements, solicitation and review of applications, full life-cycle management of awards, as well as program evaluation and planning.<sup>11</sup> The JPCs support the DHA Research and Development Director in the planning, programming, budgeting, and evaluation oversight of RDT&E activities relevant to the six core research program areas.<sup>11,26-31</sup>

Research is then executed through agents such as USAMRMC, USUHS, Office of Naval Research, Air Force Office of Scientific Research, and the U.S. Navy Bureau of Medicine and Surgery, as well as academia, industry, and other government agencies.<sup>11</sup>

## LINE-FUNDED MEDICAL RESEARCH

### Army

For the Army Medical Command, medical research is conducted at either Army MTFs or laboratories under the command of USAMRMC. USAMRMC manages the federally appropriated Army core budget as well as the assigned Army and DHP Congressional Special Interest funding for medical research and development.<sup>41</sup> A majority of USAMRMC Congressional Special Interest funds are then executed through the CDMRP, U.S. Army Medical Materiel Development Activity, or the U.S. Army Medical Materiel Agency.<sup>41</sup> Army medical research conducted using either Army core or DHP RDT&E funds can be executed through USAMRMC component laboratories and research institutes, such as the U.S. Army Institute for Surgical Research; USAMRMC subordinate laboratories, such as the U.S. Army Medical Research Institute of Infectious Diseases; or special foreign activities, such as the U.S. Army Medical Research Unit – Kenya.<sup>41</sup>

### Navy

Navy medical research is divided between Science and Technology and Advanced Development. The Office of Naval Research is the Navy authority for Science and Technology programs and “coordinates, executes, and promotes the Science and Technology programs of the Navy and



Marine Corps.”<sup>41</sup> The Office of Naval Research’s Warfighter Performance Department manages a majority of the Navy’s medical research under the direction of the Force Health Protection pillar of the Future Naval Capability program. The U.S. Navy Bureau of Medicine and Surgery oversees the majority of Navy Advanced Development medical research. For Navy medical RDT&E research, the Naval Medical Research Center is both the headquarters for seven subordinate RDT&E laboratories and a major research laboratory. Navy medical RDT&E laboratories are located in the continental United States and overseas, such as the Naval Health Research Center in San Diego, California and the Naval Medical Research Center – Asia in Singapore. Navy medical research is also conducted within the Navy systems commands under sponsorship of the Assistant Secretary of the Navy and Marine Corps for Research Development and Acquisition, as well as the Naval Postgraduate School and the Naval War College.<sup>41</sup>

### **Air Force**

The Air Force Medical Support Agency Directorate for Research and Acquisition oversees Air Force medical research funding. A majority of Air Force medical research is then executed through two platforms, the 59th Medical Wing at Joint Base San Antonio and the Air Force Research Laboratory’s 711th Human Performance Wing at Wright-Patterson Air Force Base in Dayton, Ohio.<sup>41</sup>

### **UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES**

USUHS, a DoD university, reports to the ASD(HA).<sup>43</sup> The Office of the Vice President for Research facilitates, promotes, and oversees all of USUHS’s research activities. Approximately 80 funding organizations support USUHS’s research activities.<sup>44</sup> Medical research and development is funded intramurally using DHP RDT&E funds,<sup>45</sup> or it can be funded using extramural sources. Of note, the Henry M. Jackson Foundation for the Advancement of Military Medicine was authorized by Congress to support research at USUHS<sup>46</sup> and facilitates the use of funds to provide staffing, program and financial management, and administrative and logistical support.<sup>47</sup> DHP RDT&E research at USUHS can be conducted through programs such as the Armed Forces Radiobiology Research Institute,<sup>48</sup> Biomedical Instrumentation Center,<sup>49</sup> or Center for Laboratory Animal Medicine.<sup>50</sup>

### **CLINICAL INVESTIGATION PROGRAMS**

The CIPs support Graduate Health Sciences Education (e.g., Graduate Medical Education [GME]) and other allied health programs of the Services, as well as promote professional standing and accreditation of health education and training programs within the MHS.<sup>18</sup> CIP activities are generally carried out at MTFs or dental/medical clinics. Under the purview of the USD(P&R), the Research Regulatory Oversight Office oversees “intramural and extramural research activities involving humans and animals to ensure compliance with legal and ethical requirements,”<sup>51</sup> including clinical investigations conducted in the MHS.<sup>51</sup> Each of the CIP representatives of the Military Departments, National Capital Region Medical Directorate (NCR MD), and USUHS provide an annual report to the ASD(HA) on their CIP activities.<sup>18</sup> However, this is not a report that is readily available to the public.



In contrast to DHP RDT&E funds that are designated by budget activities, the CIPs primarily rely on DHP O&M funding, which is designated by Budget Activity Groups.<sup>1</sup> Clinical investigations may also be conducted using grants from federal agencies (e.g., NIH) or tax-exempt corporations, foundations, funds, or educational institutions operated primarily for scientific, literary, or educational purposes. CIP funding is included in the In-House Care Budget Activity Group for the Navy<sup>52</sup> and the Consolidated Health Support Budget Activity Group for the Army<sup>53</sup> and Air Force.<sup>54</sup> In contrast to DHP RDT&E funds, DHP O&M funds are only available for obligation for one FY.<sup>18</sup>

DoDI 6000.08 states that CIPs may receive DHP RDT&E funding for clinical investigations on health problems encountered by DoD eligible beneficiaries if they are in support of human clinical trials in the DHP RDT&E research areas.<sup>18</sup> Additionally, “CIP may receive funding on a case by case basis from non-DHP research funds in accordance with applicable federal laws and written agreements with the non-DHP sponsor.”<sup>18</sup> However, throughout roundtable discussions with DoD investigators, it was made evident to the DHB that many MTFs are hesitant to accept DHP RDT&E funds to support CIPs.

In contrast to the DHP RDT&E program, CIPs are managed separately by each Military Department (Army, Navy, and Air Force) and the DHA’s NCR MD and USUHS, given their Title 10 authority to man, train, and equip.<sup>55-57</sup> Listed below is an overview of the oversight and execution of clinical investigations by the Services, the DHA NCR MD, and USUHS.

## Army

The Army Surgeon General prepares policies and regulations related to Army CIPs.<sup>58</sup> Within Army medical centers, the commander is responsible for all clinical investigations conducted at their center. The medical center commander also must “organize a clinical investigation support system within a separate hospital organizational structure to implement the CIP” and “appoint a clinical investigation committee, a [human use committee], and an [animal use committee].”<sup>58</sup> Commanders of MTFs or dental treatment facilities are directed to use their regional medical center’s Department of Clinical Investigation (DCI) for clinical investigation support, or they may seek approval from headquarters (U.S. Army Medical Command) for clinical investigation support.<sup>58</sup> Army’s regional DCIs support all clinical research that occurs in their respective and nearby MTFs; DCIs do not support clinical research activities conducted at USAMRMC subordinate laboratories.<sup>59</sup> DCIs also support the IRBs at Army MTFs.<sup>41</sup> After approval by the DCI, clinical research projects have a second-tier review at USAMRMC Office of Research Protection’s (ORP’s) Human Research Protections Office (HRPO). For the Army, all proposals and protocols funded by USAMRMC must be reviewed by the HRPO to ensure that all requirements are met.<sup>41</sup> The Army recently directed the transition of its Clinical Investigations Regulatory Office, previously a subordinate office of USAMRMC ORP, to the Clinical and Translational Research Program Office.<sup>60</sup> The Clinical and Translational Research Program Office, stood up June 2016, manages the Army CIPs on behalf of the U.S. Army Medical Command under DoDI 6000.08. This office reports to the provisional U.S. Army Medical Command Assistant Surgeon General/Deputy Chief of Staff for Quality and Safety.<sup>60</sup>



## Navy

The Navy Surgeon General, also the Chief of the U.S. Navy Bureau of Medicine and Surgery, is responsible for establishing Navy CIP policy and maintaining oversight.<sup>61</sup> On behalf of the Navy Surgeon General, the Special Assistant for Clinical Research and Director, CIP, is the program manager for Navy CIPs. Commanders of Navy Medical Regions oversee clinical investigation activities within their region, and commanders of Navy MTFs oversee clinical investigations within their command. Within MTFs, Directors of Clinical Investigation Departments (CIDs) act as program managers and are a central point of contact for Navy investigators.<sup>61</sup> The U.S. Navy Bureau of Medicine and Surgery CIDs are located at Naval Medical Center Portsmouth and Naval Medical Center San Diego,<sup>41</sup> and they provide support to research efforts of the medical staff, as well as administrative support for the Navy Medicine East and Navy Medicine West regional IRBs. All levels of research review and determinations are made by CIDs or at the respective Navy Research and Development laboratory with research administrative support.<sup>41</sup> The Department of the Navy Human Research Protection Program (HRPP) ensures compliance with federal and local laws and regulations related to human subjects research. Navy MTF or research and development laboratory commanders then provide final approval of research projects.<sup>41</sup>

## Air Force

Similar to the Army and Navy, the Air Force Surgeon General is responsible for Air Force clinical investigations under a program called the Clinical Investigation and Human Use Program (CIHUP).<sup>62</sup> The major command surgeon and installation commander are responsible for “CIHUP support and program compliance oversight for all CIHUP sites,”<sup>62</sup> and the “MTF Commander and Air Force Laboratory Director are responsible for implementing the CIHUP.”<sup>62</sup> The Clinical Investigation Facilities (CIFs) in the Air Force support all research efforts within the MTF where a CIF is located, as well as GME programs.<sup>41</sup> Before any clinical research is conducted, the Air Force Research Oversight and Compliance Division and their designated human research protection officials provide regulatory reviews on behalf of the Air Force.<sup>41</sup>

## National Capital Region Medical Directorate

The DHA’s NCR MD exercises authority, direction, and control over seven dental, health, and medical centers, including WRNMMC, Fort Belvoir Community Hospital, and the Joint Pathology Center.<sup>63</sup> For the NCR MD, the Department of Research Programs at WRNMMC supports investigators at WRNMMC, Fort Belvoir Community Hospital, and the Joint Pathology Center to “facilitate research and ensure that all regulatory standards are met.”<sup>64</sup> The Department of Research Programs has staff dedicated to research development, regulatory oversight, and compliance.<sup>64</sup>

## Uniformed Services University of the Health Sciences

The Office of the Vice President for Research oversees all research activities at USUHS.<sup>44</sup> USUHS provides many opportunities for clinical investigations, such as through its Clinical Research Unit,<sup>65</sup> as well as its various centers and programs, such as the Center for Neuroscience and Regenerative Medicine,<sup>66</sup> the Infectious Disease Clinical Research Program,<sup>67</sup> or the



Collaborative Health Initiative Research Program.<sup>68</sup> Also stated previously, the Henry M. Jackson Foundation is Congressionally authorized to support research activities at USUHS.<sup>47</sup> It was briefed to the DHB that non-profits, such as the Henry M. Jackson Foundation, have been useful for facilitating the management of DHP O&M funds and thus providing the needed flexibility to expend funds past one FY. This has been particularly useful for DoD's multi-site clinical studies.

## CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

In response to lobbying patient advocacy groups, Congress authorized funds in 1993 to support breast cancer research managed by DoD, creating the "CDMRP to develop, direct, and manage an innovative agenda for breast cancer research."<sup>69</sup> The CDMRP has since evolved to include 28 funded research programs both within and outside DoD addressing a variety of diseases ([Table 2, Appendix B.3](#)) and is located within USAMRMC;<sup>70</sup> funding is "a direct response to the needs of Service Members and their families, research communities, and the public at large."<sup>11</sup> Funding for the CDMRP is not included in DoD's requested budget as "dollars for the CDMRP are not considered part of the DoD's core mission."<sup>71</sup> Therefore, "the dollars to fund CDMRP are added every year during the budget approval cycle by members of the House or Senate, in response to requests by consumer advocates and disease survivors."<sup>71</sup> As such, the funded research programs under CDMRP may change yearly, based on funding.<sup>11</sup> Of note, in FY 2015, \$1.08 billion of the \$1.7 billion DHP RDT&E budget (over 60 percent) was Congressional Special Interest medical research executed through the CDMRP ([Figure 2](#)).

Further information on DHP medical research oversight and execution can be found in [Appendix B](#).

### 1.5 INFRASTRUCTURE FOR DEFENSE HEALTH PROGRAM MEDICAL RESEARCH

Beyond the basic management and execution of medical research, key elements of infrastructure are critical to supporting the Department's medical research mission. The unique elements of an optimal medical research infrastructure may vary depending upon the research being conducted, and thus the DHB has focused its review on a few common elements of research infrastructure necessary for the DHP medical research enterprise, such as regulatory support (e.g., IRBs), technology transfer support, personnel (e.g., clinical research coordinators, protocol development staff, and biostatisticians) and facilities.

Challenges associated with the lack of supportive research infrastructure in DoD were noted throughout conversations DHB had with active duty and civilian investigators and have been noted by others in past reports.<sup>14,72</sup> Unfortunately, research infrastructure challenges are prevalent across the military medical research enterprise, particularly for clinical investigations. Without proper staffing, research coordination and administrative support, facilities, and sufficient resourcing, DoD investigators are left to navigate the intricate medical research regulatory pathways and processes alone.<sup>73</sup> This can result in wasted time, inefficiencies, irregular policies and procedures, and missed opportunities to advance DoD's research mission.



## DEPARTMENT OF DEFENSE AND SERVICE-SPECIFIC POLICIES, ROLES, RESPONSIBILITIES, AND INFRASTRUCTURE SUPPORT PROVIDED FOR HUMAN SUBJECTS RESEARCH

A number of federal regulations govern research involving human subjects. The Department of Health and Human Services regulations, 45 Code of Federal Regulations part 46, include four subparts: A, B, C, and D; subpart A is frequently referred to as the “[Common Rule](#),” and subparts B-D provide additional protections for vulnerable populations.<sup>74</sup> The Federal Policy for the Protection of Human Subjects, also known as the Common Rule, was published in 1991 and codified in separate regulations by 15 federal departments and agencies, including DoD.<sup>74</sup> The Common Rule describes basic requirements for IRB composition, review criteria, and operations; obtaining and documenting informed consent; and obtaining Assurances of Compliance with the regulations for research covered by the policy. Each federal department and agency adopts the identical language of the Common Rule,<sup>74</sup> and DoD’s equivalent to the Common Rule is 32 Code of Federal Regulations part 219.

Human subjects research conducted or supported by DoD is governed by both 32 Code of Federal Regulations part 219<sup>75</sup> and 10 U.S. Code section 980 *Limitation on Use of Humans as Experimental Subjects*.<sup>76</sup> The ASD(R&E) is the principal liaison for research involving human subjects conducted or supported by DoD and provides guidance and procedures necessary to carry out human subjects research through DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*.<sup>77</sup> The ASD(R&E) also has the authority to “exercise the authorities of the Head of the Department” identified in the Common Rule and “establish a process to oversee the DoD Components’ implementation of their respective Component HRPP management plan and compliance with this Instruction,” among other responsibilities.<sup>77</sup>

The ASD(R&E) also consults with the ASD(HA) for medical research involving human subjects.<sup>77</sup> The ASD(HA) “advise[s] the ASD(R&E) on matters related to the participation of human subjects in research, especially regarding medical safety, bioethics, and standards of professional health care and conduct,” and represents DoD “on matters relating to implementation of FDA [U.S. Food and Drug Administration] regulatory requirements.” Additionally, each of the Services has their own policy to implement DoDI 3216.02.<sup>62,78-81</sup>

In addition, as required by 10 U.S. Code Section 980, funds appropriated to DoD may not be used for research involving a human being as an experimental subject unless the informed consent of the subject is obtained in advance; or in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.<sup>76</sup>

### **Army**

A number of organizations are responsible for the oversight of research involving human subjects sponsored or conducted by the Army.<sup>82</sup> USAMRMC ORP: 1) ensures that USAMRMC-conducted, -contracted, -sponsored, -supported, or -managed research and USAMRMC investigations involving human subjects, human anatomical substances, or animals are conducted in accordance with federal, DoD, Army, USAMRMC, and international regulatory



requirements; 2) provides guidance regarding USAMRMC human subjects protection and animal welfare policies and procedures; and 3) develops educational activities for persons conducting or managing research and implements an active compliance oversight program.<sup>82</sup>

USAMRMC ORP has three subordinate offices: HRPO, IRB Office, and Animal Care and Use Review Office.<sup>82</sup> The ORP HRPO is the principal advisor to USAMRMC for human subjects protection and develops and implements human subjects policies and regulations.<sup>83</sup> On behalf of USAMRMC, the ORP HRPO also reviews and approves intramural and extramural human subjects protocols and conducts human subjects protection site visits.<sup>83</sup> USAMRMC-funded human subjects research must be approved by the ORP before funds are used to support the investigation.<sup>41</sup>

Army regional DCIs support the IRBs at Army MTFs.<sup>41</sup> USAMRMC has its own IRB that is supported by the IRB Office. The IRB Office is responsible for IRB review, approval, and oversight for human research conducted by scientists assigned to USAMRMC; select USAMRMC subordinate Institutes and Laboratories; and select non-USAMRMC DoD institutions.<sup>84</sup> The Army also has an Army HRPO, which assesses and approves Army HRPPs; develops and disseminates Army regulations, policy, and guidance related to human subjects research; and ensures regulatory compliance, such as FDA and Health Information Portability and Accountability Act requirements.<sup>85</sup> The Army HRPO also negotiates new DoD Assurances and oversees the renewal of existing Assurances for all Army institutions and provides headquarters-level administrative review.<sup>85</sup>

## **Navy**

The Department of the Navy's HRPP is located in the Navy Surgeon General's Office, and it develops and implements Navy policies and procedures for the protection of human research subjects.<sup>86</sup> The Department of Navy HRPP reviews and approves DoD/Department of Navy Assurances; monitors and oversees human research protocols through headquarters-level administrative review processes; and supports the review and approval of research protocols, as needed.<sup>86</sup> Research review and determinations are either provided by Navy's CIDs or by Navy Research and Development laboratories with research administrative support; commanders of these institutions provide final approval.<sup>41</sup> Scientific review must be conducted before IRB review; however, these procedures may vary among Navy commands.<sup>41</sup>

## **Air Force**

The Air Force Surgeon General is responsible for establishing and properly resourcing the Air Force HRPP, including the Air Force Medical Support Agency Research Oversight and Compliance Office, "to ensure protection and welfare of human subjects in research supported or conducted by the [Air Force]."<sup>62</sup> Under the authority of the Air Force Surgeon General, the Air Force Medical Support Agency Research Oversight and Compliance Office oversees implementation and operation of the Air Force HRPP.<sup>81</sup>

The Air Force Medical Support Agency Research Oversight and Compliance Office also provides support and expertise to the Air Force HRPP, coordinates policy and interprets



regulations, and issues guidance and procedures.<sup>62</sup> The Air Force Medical Support Agency Research Oversight and Compliance Office and its designated human research protection officials provide the reviews necessary to ensure all federal, DoD, and local requirements are met.<sup>41</sup> Air Force MTF commanders and Air Force laboratory directors are responsible for implementing CIHUPs in human-use laboratories, CIFs, and MTFs.<sup>62</sup> IRBs at CIFs support Air Force MTFs with research involving human subjects.<sup>41</sup>

### **National Capital Region Medical Directorate**

Clinical research conducted in the NCR MD is supported by the Department of Research Programs, headquartered at the WRNMMC. The Department of Research Programs at WRNMMC has a number of offices that support research, including a Business Cell;<sup>87</sup> Research Development,<sup>88</sup> Research Oversight,<sup>89</sup> and Research Compliance offices;<sup>90</sup> and the Center for Nursing Science and Clinical Inquiry.<sup>91</sup> Language in the FY 2017 NDAA states the Director of the DHA will be responsible for administration and management of all MTFs beginning October 2018, but it is unclear whether this will also direct centralization of research support infrastructure under the DHA.<sup>23</sup>

### **Uniformed Services University of the Health Sciences**

USUHS has a Human Research Protections Program Office located within the Office of Regulatory Compliance under the Office of the Vice President of Research.<sup>92</sup> The Human Research Protections Program Office is responsible for implementing the DoD Assurance and is the custodian of the Department of Health and Human Services Federalwide Assurance at USUHS.<sup>92</sup> The Human Research Protections Program Office also provides administrative support to USUHS's two IRBs: USUHS IRB I and the Infectious Disease Clinical Research Program IRB. The Infectious Disease Clinical Research Program IRB is a unique DoD IRB; it creates a single review pathway for multi-center infectious disease research and eliminates the need for multiple and repetitive scientific, ethical, and second level reviews at multiple MTFs.<sup>67</sup> Further, the Human Research Protections Program Office implements and provides training and guidance on human subject research regulations and requirements for USUHS faculty, staff, and students.<sup>92</sup>

## **ADDITIONAL REQUIREMENTS FOR DEFENSE HEALTH PROGRAM MEDICAL RESEARCH**

Apart from human subjects research protections, there are other research requirements that DoD investigators may be required to comply with, depending on the type of research conducted. For example, the research protocol may require reviews by an Institutional Animal Care and Use Committee,<sup>93</sup> an Institutional Biosafety Committee,<sup>94</sup> a privacy board,<sup>95</sup> or the protocol investigators may have to undergo a conflict of interest review.<sup>77</sup>

## **INSTITUTIONAL REVIEW BOARD OPERATIONS AND TECHNOLOGY**

All DoD-conducted or -supported research involving human subjects is governed by DoDI 3216.02,<sup>77</sup> and each of the Services has its own policy related to protection of human subjects in research that provide direction on the operation of IRBs.<sup>62,78-81</sup> Challenges associated with IRB processes have been documented in literature related to both DoD and non-DoD research,



describing issues such as expanding obligations of IRBs beyond the protection of research participants,<sup>96</sup> excessive study paperwork, strict regulatory requirements, study delays,<sup>97</sup> and increased expenses.<sup>98-104</sup>

Currently, there is no standardization of DoD IRB forms and processes;<sup>72,73</sup> each Service and federal agency has different requirements and different methods for implementation of the federal laws governing human subjects research. Further, each Service and the institutions within that Service interpret the implementation of the laws differently.<sup>73</sup> The Army recently agreed to utilize a single protocol template for all Army MTFs; however, the Navy, Air Force, and DHA continue to use forms that contain similar information in different formats, making it challenging to coordinate multi-site studies across the Services.<sup>72</sup> With the launch of the MHS's new electronic IRB system in April 2016, DoD investigators will have standardized templates "with smart forms and embedded logic to guide research teams through the entire submission process."<sup>105</sup> The DHB was made aware that efforts are underway to standardize forms and processes through the electronic IRB system; however, as of October 2016, not all DoD institutions were online with the electronic IRB system.<sup>106</sup>

The DHB also frequently heard that for multi-site or multi-center studies, multiple IRB reviews were still occurring when a single IRB review would be adequate. This may be because principal investigators may not be aware that reliance on a single DoD IRB is possible, or there may not be a support system in place to help a principal investigator achieve a single IRB solution. With a few exceptions (e.g., the Infectious Disease Clinical Research Program IRB), DoD's IRB system as a whole is currently decentralized. In contrast, at the NIH, the use of a single IRB for multi-site research is now a mandate.<sup>107</sup> Although moving to a single IRB system would eliminate duplicative ethics reviews, it would not eliminate the necessary reviews and requirements for a performance site's HRPP, such as departmental reviews; institutional education, training, and credentialing requirements; or post-approval compliance monitoring.<sup>78,79,81</sup>

The DHB also heard from IRB staff and DoD investigators that delays may be encountered related to protocols that are poorly designed and to slow responses from investigators to IRB stipulations. Additionally, DoD IRBs may not have sufficient IRB staff, and they may be overwhelmed with increased workloads. The previous DoD IRB system, IRBNet, collected metrics evaluating processes, as will the new DoD electronic IRB. Such metrics may be useful predictors of IRB effectiveness, helping to improve the conduct of DoD human subjects research.<sup>108</sup> However, although these metrics may be informative, they do not directly measure the effectiveness of an IRB in protecting the welfare of human subjects.<sup>108</sup>

Despite these challenges, there has been positive movement forward to improve IRB operations. For example, the DHB was notified in August 2016 that the Army will consolidate its medical center IRBs into regional IRBs and will reduce from 10 to 5 medical IRBs.<sup>109</sup> Additionally, the implementation of the new electronic IRB should help drive standardization of templates and facilitate agreements to accept the other Service's IRB review.<sup>110</sup>



## COLLABORATIVE RESEARCH

There are several variations of collaborative research; for example, collaborative research may involve investigators from two different departments of the same institution or a research project involving the federal government and an academic institution or private company.<sup>111</sup>

Investigators may pursue a collaborative research project for various reasons, such as answering research questions, sharing responsibility, increasing funding opportunities, or gaining greater credibility. In addition, the enormous wealth of data or resources available in DoD provides an extraordinary opportunity for collaborative medical research.<sup>41</sup>

Despite these benefits, there are challenges associated with collaborative research. For instance, each of the Services has its own policy related to the protection of human subjects in research,<sup>62,78-81</sup> which may delay a multi-site/multi-center research project. For multi-site/multi-center research conducted by DoD, IRBs often agree to rely on one IRB through Institutional Agreements for IRB Reviews. However, investigators at each site are responsible for obtaining local command approval, as required per site.<sup>41</sup> Further, between agencies such as DoD and the Department of Veterans Affairs (VA), a minimum of two IRB reviews is required, as DoD and the VA cannot engage in Institutional Agreements for IRB Reviews given differing review regulations.<sup>41</sup>

There are also challenges related to credentialing and training requirements, the rotation of staff, changes in leadership, and a lack of protected research time.<sup>41</sup> Additionally, the process for executing cooperative research and development agreements (CRADAs) and interagency agreements may be barriers for collaborative research. CRADAs are not standardized across the Services and may be lengthy to process; each of the Services uses its own CRADA template.<sup>41,112</sup> For interagency agreements, there are different regulations governing different agencies.<sup>113</sup> These issues may delay the initiation of collaborative research or threaten the continuity or completion of research activities, as well as discourage collaboration with DoD investigators.

### Visibility of Projects for Collaborative Medical Research

Having accessible information on planned and ongoing research efforts helps coordinate and accelerate collaborative research.<sup>114</sup> A February 2012 Government Accountability Office (GAO) report found that “information on health research funded by the NIH, DOD, and VA is in different databases with varying types and amounts of information.”<sup>115</sup> The GAO recommended that the NIH, DoD, and VA “determine ways to improve access to comprehensive electronic information on funded health research shared among agency officials and improve the ability of agency officials to identify possible duplication.”<sup>115</sup> Later that year, the ASD(HA), CDMRP, NIH, and VA convened to address a way to use the NIH Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER) for a pilot program.<sup>116</sup> During this time, the NIH developed and tested Federal RePORTER, based on the NIH RePORTER module.<sup>116</sup>

At the time of the publication of the 2013 National Research Action Plan, the VA was already using the NIH RePORTER.<sup>114</sup> Between 2013 and 2014, the ASD(HA) identified the CDMRP as the organization to administer a pilot project enabling visibility of DHP RDT&E-funded medical research through the Federal RePORTER, and the JPC Chairs were directed to plan for improved data sharing using the NIH’s Federal RePORTER and Electronic Research Administration



Commons.<sup>116</sup> The pilot project, previously scheduled to end by FY 2016,<sup>116</sup> is underway, but has experienced delays in execution. The CDMRP has encountered various challenges related to data transfers of the DHP RDT&E-funded projects to Federal RePORTER; however, CDMRP has continued to transfer data on over 4,800 DHP RDT&E project records using alternative methods.<sup>117</sup>

## TECHNOLOGY TRANSFER

Technology transfer is the process of sharing, transmitting, or conveying technology data and information between government agencies, industry, and academia.<sup>118</sup> The general criteria required for a successful technology transfer program in the government include having an effective Office of Research and Technology Applications (ORTA), engaged researchers, well-managed intellectual property, effective transfer mechanisms, efficient processes, and meaningful communication with industry.<sup>119</sup>

There are multiple technology transfer mechanisms available, including [CRADAs](#), [licensing agreements](#), [material transfer agreements](#), and [interagency agreements](#);<sup>120,121</sup> much of the activity in the ORTAs is focused around the establishment of CRADAs, given the high demand and value they reap DoD and the industry.<sup>122</sup> Technology transfer mechanisms, such as CRADAs, enable the collaborative leveraging of federal and non-federal resources to more efficiently develop products and expertise.

Although currently the Office of the Under Secretary of Defense for Acquisition, Technology and Logistics establishes policies for research and development across DoD, technology transfer activities are not managed centrally; instead, each Service and each laboratory's ORTA manage them.<sup>151,152</sup> For example, it was stated to the DHB that the entire Department of the Navy has approximately 35 laboratories with distinct ORTAs. Each of the Services has demonstrated technology transfer initiatives, such as the Army Research Laboratory's Open Campus initiative,<sup>123</sup> the Navy's Innovation Discovery Process and Military to Market program,<sup>119</sup> and the Air Force Research Laboratory's Information Directorate.<sup>124</sup> However, there is a lack of harmonized and consolidated technology transfer policies, procedures, and templates across the Services. This leads to difficulties working across Services and sends conflicting messages to outside collaborators.

The Services' technology transfer programs may vary greatly in their expertise of medical technology transfer and in the depth and experience of ORTA and legal staff, particularly intellectual property support. The Services each provide their own patent support, which operate differently, and the DHA does not have its own patent support; currently, DHA intellectual property needs are supported by the Naval Medical Research Center. The ORTAs may be unable to complete their requisite tasks because of a large scope of responsibilities and insufficient capacity.<sup>122</sup> Therefore, DoD laboratories may enter into Partnership Intermediary Agreements to complete many of the tasks ORTAs are unable to support, such as conducting market research, as well as facilitate technology transfer activities into the private sector.<sup>125</sup>



DoD Instruction 5535.8 states that the Directors of Defense Agencies, such as the DHA, are responsible for accomplishing technology transfer in their organization.<sup>126</sup> Therefore, a critical component for the effective management of medical research within the DHA is the adoption of standardized technology transfer approaches. On July 1, 2014, the Director of the Defense Laboratory Office, under the Office of the Assistant Secretary of Defense for Research and Engineering, sent a memorandum to the DHA Research and Development Director stating that the Agency needs to develop a common set of technology transfer policies, procedures, and practices.<sup>127</sup> The memorandum continues, “A harmonization of policies, procedures, and practices in [technology transfer] for DHA . . . will enhance DHA's ability to execute its medical research, development, and acquisition mission.” In response to this memorandum, as of February 2017, a DHA technology transfer program procedural instruction has been drafted and is being routed through the DHA publication process.<sup>128</sup>

There are numerous benefits associated with transferring DoD-developed technologies. For example, transferring DoD-developed technologies may strengthen the U.S. industrial base, create acceptance for commercial off-the-shelf products for government use at reduced costs, or create technology that has applications to both industry and military.<sup>129</sup> Additionally, commercialization of DoD's innovations lowers unit costs, drives innovation, and ensures product support.<sup>121</sup> Furthermore, under licensing agreements, DoD laboratories benefit from fees and royalties, which may be used to reward the inventors, promote innovation, and support the laboratories' technology transfer programs.<sup>122</sup> A 2016 analysis demonstrated that technology transfer provided an economy-wide impact of \$48.8 billion in output from DoD license agreements, as well as the creation of 182,985 jobs with an average salary of \$71,000.<sup>130</sup>

## RESEARCH SUPPORT

In addition to the principal investigator, there are multiple members within a research team who are essential for the initiation and conduct of research activities, such as clinical research coordinators, protocol development staff, or biostatisticians. However, the availability of these essential research support staff varies between DoD institutions, especially at MTFs.<sup>41</sup> Further, civilian and contract staff must conduct research activities only as outlined in their position description and the project's statement of work.<sup>41</sup> Finally, contract staff funded with science and technology dollars performing research within MTFs or research laboratories may not provide clinical care unless privileged by the facility or under the clinical privileges of an assigned provider.<sup>41</sup>

DoD research institutions often need to rely on outside, temporary funding to hire essential research support personnel, such as through not-for-profit foundations or contracts.<sup>41</sup> However, bringing on research staff through contracts may be delayed significantly depending on the contract mechanism used and degree of infrastructure available.<sup>41</sup> Additionally, contract support staff may not receive benefits such as health care, vacation, or sick leave.<sup>41</sup> As such, there may be attrition of contract staff and less research support staff available to DoD investigators.

DoD began an initiative in FY 2012 using DHP RDT&E program element 6.6 funds to help maintain or expand clinical research capabilities and research support personnel at numerous research sites and MTFs across DoD.<sup>131</sup> However, the DHB has been informed that although



certain MTFs, such as the Naval Medical Center San Diego, have taken advantage of this program, there has been hesitancy to participate by other MTFs.

Other critical elements for DHP medical research are the facilities in which research is conducted, such as medical laboratories. In a 2011 Center for Strategic and International Studies report on overseas medical laboratories, the authors highlighted the lack of sufficient, predictable, and sustainable core funding.<sup>14</sup> The authors noted the lack of core funding often drives laboratories to “take on research and program opportunities beyond their primary missions.”<sup>14</sup> [As noted previously](#), this may lead to opportunity costs, diverted resources (e.g., research personnel and infrastructure), and may compromise the primary mission of DHP medical research. This was also echoed in a 2015 GAO report on DoD’s chemical and biological defense facilities, such as the U.S. Army Medical Research Institute of Infectious Diseases.<sup>37</sup> Officials from the U.S. Army Medical Research Institute of Infectious Diseases informed GAO that it would be beneficial if the Chemical and Biological Defense Program Enterprise provided stable, sustainment funding in a manner similar to the funding received for the test and evaluation facilities.<sup>37</sup>

Despite these challenges, there are a number of positive efforts to provide the infrastructure support needed for DHP medical research, such as the Army’s Clinical and Translational Research Program Office,<sup>38</sup> the Navy’s Research Methods Training Program at Naval Medical Center San Diego,<sup>132</sup> the Air Force’s 59th Medical Wing Clinical Research Division,<sup>133</sup> and the Department of Research Programs at the WRNMMC.<sup>64</sup>

Further information on infrastructure for DHP medical research can be found in [Appendix C](#).

## 1.6 PROFESSIONAL DEVELOPMENT OF DEPARTMENT OF DEFENSE INVESTIGATORS

DoD offers numerous opportunities for both military and civilian personnel to conduct medical research. However, a number of factors have led to the loss of experienced medical research talent over the last decade, including both military and civilian personnel with clinical and/or scientific expertise. This attrition is related to a number of issues, including: fiscal pressure, increasing administrative burden, repeated deployments in support of combat operations, lack of clarity on research tracks, and the perception that medical research is not valued in tangible ways, such as enhancing ones’ prospects for promotion.

Thus, young investigators are left with fewer experienced mentors and a perception that there are limited opportunities for advancement in a research career path. Further, as described in the 2015 DHB report, *Continuing Education for Department of Defense Health Professionals*, DoD policies have restricted the ability of investigators to attend professional conferences,<sup>134,135</sup> leading to limited presence of DoD investigators in these important meetings; reduced visibility and sharing of DHP medical research; and reduced opportunities to network and create research partnerships.<sup>136</sup>



## RECRUITMENT, DEVELOPMENT, AND RETENTION OF DEPARTMENT OF DEFENSE INVESTIGATORS

Qualified individuals may become military health professionals through direct commission into a Service, through USUHS, or through the Health Professionals Scholarship Program.<sup>137</sup> For active duty military personnel, opportunities to conduct medical research exist at DoD research laboratories and MTF CIPs. Those military personnel with the appropriate education and training can conduct research at dedicated research facilities, such as the Walter Reed Army Institute of Research, Naval Medical Research Center, or Air Force Research Laboratory. Further, personnel may pursue an academic affiliation (e.g., faculty, student, or resident) with a civilian or military institution.<sup>41</sup> There appears to be no intentional recruitment, however, of officers with medical research training. Individuals are recruited because of their clinical skills with little or no thought given to their research qualifications.

Civilian DoD personnel may conduct research as a clinician at an MTF or may be hired as a scientist by a DHP medical research laboratory. Similar to military personnel, civilian personnel may hold faculty positions at military or civilian institutions or conduct research as a trainee in a military education program. Funding sources for civilian personnel vary by Service and include federal and contract positions.<sup>41</sup>

### Challenges for Retaining Active Duty Investigators

Between 2007 and 2009, multiple assessments of the recruitment and retention of military health professionals identified significant shortages in physicians, nurses, dentists, and other medical officers.<sup>137-139</sup> The assessments cited various challenges in recruitment and retention, including the limited supply of and high demand for qualified health professionals; the lower pay than the private sector; and the stresses, length, and frequency of deployment, among other challenges.<sup>139</sup> To improve recruitment, the Services occasionally offer accession bonuses or special pay for medical officers in certain specialties, though special pay for research activities is limited across the Services.<sup>140</sup>

Past literature cites the frequent rotation of active duty personnel as a challenge in conducting medical research in DoD.<sup>8,14</sup> The relocations may cut short long-term research projects, impede the mentorship of younger scientists, or slow the career progression of scientists.<sup>14</sup> Throughout the DHB's roundtable discussions with DHP medical research policy leaders, as well as military investigators at all levels of experience, it was clear that medical research was not perceived as significantly valued in an officer's evaluation for promotion, particularly for those conducting clinical research at MTFs.

Each Service has a number of research-oriented career paths under the Medical Service Corps or Biomedical Sciences Corps (e.g., microbiology, research physiology, or behavioral health); however, for the Services' Nurse Corps, Medical Corps, and Dental Corps, few published descriptions of medical research career paths were identified.<sup>141-143</sup> A 2011 Center for Strategic and International Studies report recommended creating a dedicated medical research career track to provide improved incentives for research.<sup>14</sup> Such a track might include special pays for those



engaged in medical research. Such special pays are currently available for commissioned officers in the U.S. Public Health Service.<sup>144</sup>

The FY 2017 NDAA demonstrates that there is an evolutionary change occurring in how the MHS is approaching health care administration, such as the movement toward value-based health care, adoption of core quality performance metrics, and accountability of certain leaders for the performance of the MHS.<sup>23</sup> The MHS currently uses relative value units (RVUs) to measure productivity.<sup>1</sup> Patient care contributes to generating RVUs, while medical research activities do not, and DoD outlines Service- and specialty-specific targets using RVU benchmarks. The MHS goal is for at least 75 percent of providers to meet productivity targets by FY 2018,<sup>145</sup> placing commanders at MTFs under pressure to meet or exceed RVU standards. Of note, research is not viewed as a critical mission of the MTFs as evidenced by investigators voicing to the DHB that they lack dedicated research time. Clinicians motivated to conduct research or those needing to complete GME scholarly activity requirements are typically left to do so on their “own” time and not as part of their “assigned” duties.

DoD medical RDT&E laboratories and MTFs quantify investigators’ research productivity by tracking publications; presentations; new CRADAs; patents filed; and active, completed, or new protocols.<sup>146,147</sup> During discussions with DoD investigators, it was stated to the DHB that these metrics do not explicitly contribute to the performance evaluation of MTF commanders; therefore, MTF commanders may not be incentivized to promote research at MTFs, apart from achieving the minimum scholarly activity threshold as required by the ACGME.

### **Challenges for Retaining Department of Defense Civilian Investigators**

There are also challenges associated with retaining civilian DHP medical researchers. Currently, federal agencies such as DoD, Department of Health and Human Services, Department of Justice, and the VA have delegation agreements under Title 38 of the U.S. Code for employees providing “direct patient-care services or services incident to direct patient-care services.”<sup>148,149</sup> These agreements establish higher rates of basic pay for “an occupation or group of occupations nationwide or in a local area based on a finding that the Government’s recruitment or retention efforts are, or would likely become, significantly handicapped without those higher rates.”<sup>149</sup> Title 38 may only be used to hire and compensate DoD civilian physicians and dentists; Title 38 is not applicable to other health care professionals unless they are hired in the excepted service.<sup>150</sup>

The Department of Health and Human Services and the Environmental Protection Agency also have unique hiring authority under Title 42 of the U.S. Code to fill mission critical scientific and medical appointments. Title 42 enables these agencies to compensate their employees above the salary limits applicable to federal employees.<sup>151</sup> DoD does not have Title 42 hiring authority to recruit and retain high-quality scientists.<sup>150,151</sup> As a result, DoD is less competitive in hiring and retaining civilian researchers compared to other federal agencies or in the biotechnology and pharmaceutical industries for the improved monetary incentives.



## EDUCATION AND TRAINING

Scholarly activity is a Common Program Requirement for accreditation by the ACGME for all specialties.<sup>152</sup> For resident scholarly activities, it is mandated that educational program curricula “must advance residents’ knowledge of the basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care.”<sup>152</sup> Additionally, the “sponsoring institution and program should allocate adequate educational resources to facilitate resident involvement in scholarly activities.”<sup>152</sup> ACGME has Residency Review Committees for each specialty that “propose requirements for revising residency program accreditation standards and ensuring compliance with individual programs’ standards,” such as a specialty’s scholarly activity requirements.<sup>153</sup> Currently, there is no uniform definition of scholarly activity used by all Residency Review Committees, nor a standardized methodology for assessing resident and faculty scholarly activity.<sup>154</sup>

The CIPs support completion of scholarly activity requirements by promoting “accreditation of health education and training programs within the MHS,” and supporting “Graduate Health Sciences Education. . . and other allied health programs of the Military Services.”<sup>18</sup> However, with no uniform definition for scholarly activity<sup>154</sup> nor significant formal research education and training provided by medical schools, residencies, or fellowships,<sup>73</sup> clinical investigators in the DoD are at a disadvantage. Further, the trainees have limited time to complete research, may lack knowledge on how to find funding, and must meet RVU requirements based on patient care.<sup>155,156</sup> Moreover, their mentors may have limited experience themselves.<sup>155,156</sup>

Lack of proper education and training for the conduct of high-quality research can lead to poorly developed protocols, which then clog IRBs. Rather than addressing the ethical and regulatory requirements of a protocol, the IRB must address shortfalls in the protocol design. Delays may cause the research project to be left unfinished, which has implications for the ethics of the research.<sup>157</sup> The Service’s GME programs may also receive citations from the ACGME for not meeting scholarly activity requirements.<sup>158</sup>

## MENTORING

Mentoring, a reciprocal relationship in a work environment between an advanced career professional (mentor) and a beginner (mentee) aimed at promoting the career development of both,<sup>159</sup> may be divided into two categories: research mentoring and career mentoring.<sup>160-163</sup> Research mentoring involves developing the research career of the mentee through skills acquisition, selecting and conducting research projects, presenting research findings at professional meetings, writing and submitting manuscripts, protocol development, grant applications, and learning how to obtain funding.<sup>164</sup> In contrast, career mentoring may focus on career promotion, balancing professional and personal obligations, or major career decisions.<sup>164</sup> Mentoring may be formal or informal, though formal mentoring involves a more committed relationship to ensure the protégé has a successful research career.<sup>164</sup>

In 2011, the Army formed a working group to establish a leadership development program for physicians.<sup>165</sup> The working group recognized the existence of informal mentoring relationships for Army physicians, but reported that there were: insufficient time and resources to facilitate



mentoring relationships, no centralized structure to identify mentors, and little formal training related to mentoring for Army Medical Corps officers serving as mentors.<sup>165</sup> Additionally, there was a lack of executive coaching opportunities, and these opportunities were not centrally funded.<sup>165</sup> This working group did not provide specific recommendations for mentoring researchers; however, it did recommend creating a matrix cross-linking Army Medical Corps career paths (e.g., clinical, academic, research) with required education and recommended experience in order to help the Army identify physician leaders to serve as future commanders and senior leaders.<sup>165</sup>

These findings have also been reinforced throughout the DHB's roundtable discussions with DoD investigators, who noted the importance of mentorship to help navigate the complex administrative processes for initiating and conducting medical research in DoD. However, investigators frequently cited the lack of senior investigators available to provide such mentorship for junior investigators as an ongoing challenge for DoD. To bolster the next generation of DoD senior investigators, it is important for DoD to develop its cadre of junior investigators through mentorship to reduce attrition of talented personnel and create a future network of experienced research mentors to advance medical research. It is also important for the research mentor to be recognized and evaluated for their mentoring efforts.

#### INDIVIDUAL ATTENDANCE AND PARTICIPATION AT RESEARCH CONFERENCES/FORUMS

Individual participation in professional meetings and conferences by DoD's medical researchers helps to improve the visibility of DoD's contributions to medical research, including the breadth and depth of its medical research endeavors. Professional conference and meeting attendance is particularly important for early career investigators, providing them the opportunity to network and build relationships.<sup>166</sup> DoD sponsors an annual meeting, the Military Health System Research Symposium, which allows DoD investigators, academia, and industry to exchange information on research and health care advancements in military-relevant areas.<sup>167</sup> The Military Health System Research Symposium provides an opportunity to present DoD research activities, recognize successful DoD investigators, articulate MHS research priorities, and build collaborative relationships. It also provides an opportunity for DoD laboratory directors and directors of CIPs to regularly communicate on new or existing processes, policies, or regulations that hinder medical research and to facilitate early recognition of problems and their resolution.

In 2011, high profile misspending at conferences sponsored by the VA and the General Services Administration led to the publication of policies restricting conference attendance and participation.<sup>135</sup> As a result, conference review and approval processes became lengthier, and conference attendance decreased.<sup>134</sup> A 2015 GAO report identified various risks associated with changes in conference participation including a potential decline in the quality of scientific research, difficulty recruiting and retaining qualified scientists and engineers, and a diminished leadership role for DoD within the global science and technology community.<sup>134</sup> The NIH recognized the importance of conference attendance and relaxed attendance restrictions for Department of Health and Human Services investigators in the 21st Century Cures Act of 2016;<sup>168</sup> these loosened travel restrictions appear to only be afforded to investigators from the Department of Health and Human Services.



Continued restrictions on attendance of DoD investigators at professional meetings and conferences are harmful to the individual investigator, as well as the military medical research enterprise. Not participating in such venues restricts opportunities to disseminate military medical research findings and priorities, to build sustaining relationships, to advertise the unique opportunities to conduct research at MTFs and DoD medical laboratories, and to recruit talented medical researchers.

Further information on the professional development of DoD investigators can be found in [Appendix D](#).

## 1.7 ATTRIBUTION OF DEFENSE HEALTH PROGRAM MEDICAL RESEARCH

Military medical research plays a vital role in advancing patient care and population health for both civilian and military populations. However, another necessary aspect for the advancement of medicine is the dissemination of research innovations. There are a number of mechanisms to disseminate research findings, such as internal and external marketing, professional publications, and professional conferences and meetings. The DHP RDT&E portfolio supports intramural and extramural medical research;<sup>41</sup> a majority of the portfolio is extramural. Therefore, it is important that both extramural and intramural research funded by DoD is acknowledged and recognized through enhanced visibility of the contributions of DHP medical research.

### INTERNAL AND EXTERNAL MARKETING

As previously described in [Section 1.5](#), each of the Services has its own ORTA; additionally, most of the medical laboratories have an ORTA.<sup>122,169</sup> These offices develop technology transfer agreements, market the laboratory's expertise and capabilities, and conduct outreach and communications on newly patented technologies.<sup>122,169</sup> DoD also uses Partnership Intermediary Agreements, which allow federal laboratories to enter into agreements with third party intermediaries to facilitate technology transfer activities into the private sector.<sup>114</sup> These third party intermediaries complete many of the tasks that ORTAs do not have the resources to support, such as conducting market research on the value of DoD's technologies and marketplace needs.<sup>114</sup> Therefore, DoD ORTAs, Partnership Intermediary Agreements, and the research-related agreements they coordinate are important components of the marketing of DoD-developed or -funded research.

### Strategic Communication of Defense Health Program Medical Research

DoD has a wealth of unique resources for research, such as the DoD Serum Repository<sup>170</sup> and the Millennium Cohort Study,<sup>171</sup> as well as the high altitude research chambers<sup>172</sup> and operational and undersea medicine<sup>173</sup> laboratories operated by the Air Force and the Navy. Communicating the value of such resources is critical to the continued success of DHP medical research programs. However, the breadth of strategic communications of DoD's medical research capabilities and accomplishments is varied across the numerous DoD research execution agents. For example, USAMRMC publishes yearly "Command Accomplishments" reports, as well as product portfolios, strategic information papers on subordinate commands, and articles and press releases.<sup>174</sup> The Navy publishes fact sheets highlighting the capabilities and accomplishments of its medical research and development laboratories, publishes monthly newsletters,<sup>175,176</sup> and



highlights recent news articles online.<sup>177</sup> The Air Force also lists recent medical research news articles<sup>178</sup> and maintains fact sheets on the Air Force Research Laboratory<sup>179</sup> and 59th Clinical Research Division that are accessible online.<sup>180</sup>

At the institution and program level, many of the Army subordinate laboratories and some of the JPC-managed core research programs advertise recent peer-reviewed publications by their civilian and active duty investigators online. However, for the CIPs, the regional MTFs that house the Army's DCI, Navy's CID, or Air Force's CIF may not even have a website providing the mission and vision of the program; currently, none publicly advertise recent peer-reviewed publications. However, recently a MHS Studies Inventory Tool was developed to allow "easy review of recent studies that are either conducted or sponsored by the MHS, or accomplished using datasets developed or maintained by the Defense Health Agency for administrative, operational, or research purposes."<sup>181</sup> This tool provides an opportunity to highlight and provide further visibility on the health services research conducted by DoD investigators. Currently, 213 abstracts are populated into the tool; efforts are underway to populate additional, peer-reviewed health services research publications from across the MHS into the tool.<sup>182</sup>

The CDMRP publishes an annual report that provides background on the program and its research portfolio, and it includes a few pages highlighting some of the DHP RDT&E research activities under the various JPCs for which it provides execution management support.<sup>11</sup> However, there is no separate annual report of equivalent detail and length that includes both DHP RDT&E and CIPs that could be used to help market the various successes and capabilities of DHP medical research. For the CIPs, there is the previously mentioned annual report provided to the ASD(HA),<sup>18</sup> but it is not a formal report nor is it released for public distribution. Thus, there appears to be no unified strategic communications plan for DHP medical research. A unified strategic communications plan for DHP-funded medical research (both RDT&E and CIPs) would help clarify DoD's medical research priorities, its target audiences, and its available resources. One specific example that would increase visibility of DHP medical research would be a comprehensive report, such as the annual report provided by the CDMRP, highlighting various research successes from the CIPs and DHP RDT&E-funded medical research.

## PUBLICATION OF DEFENSE HEALTH PROGRAM MEDICAL RESEARCH IN PEER-REVIEWED JOURNALS

Another mechanism for attribution of DHP medical research innovations is the dissemination of such findings in peer-reviewed journals. There are a number of policies that must be followed before public dissemination of DHP medical research.<sup>41</sup> For example, the investigator must consult their relevant IRB and Public Affairs Office before publication. Further, research must be vetted by Operational Security to ensure no confidential or strategic intelligence is publicly released, and the research may need reviews by higher-level Public Affairs Offices. The Army, Navy, and Air Force all have differing procedures for clearance of research for publication, and these procedures may vary between facilities.<sup>41</sup>

Many of the medical laboratories and some of the JPCs provide lists of recent peer-reviewed publications on their websites; some lists of publications are more up-to-date than others. The visibility of such peer-reviewed publications helps highlight the innovative medical research and



productivity of DoD investigators. In addition to the standard medical literature, there are peer-reviewed journals that are venues for military-specific research or federal medicine, such as the *Medical Surveillance Monthly Report*, *Military Medicine*, and *Federal Practitioner*. DoD investigators can consult with their available bibliometric services (e.g., Walter Reed Army Institute of Research’s Gorgas Memorial Library or WRNMMC’s Darnall Medical Library) to identify the most appropriate peer-reviewed journal in which to publish their findings.

## PRESENCE AT NON-DEFENSE HEALTH PROGRAM MEDICAL RESEARCH CONFERENCES AND FORUMS

As noted previously, there are numerous benefits associated with attendance at professional conferences and meetings, including subspecialty conferences. The previously cited 2014 National Academy of Sciences report on DoD’s strategic engagement in global science and technology strongly emphasized the importance of participation in such venues, citing them as necessary for providing a venue for scientists and engineers to present their work, as opposed to journal papers; allowing researchers to network and build research collaborations; maintaining global science and technology awareness through a diversity of inputs; and preventing DoD in-house research from becoming “insular and noncompetitive.”<sup>166</sup>

The authors added that DoD should have an in-person presence at international science and technology forums to establish for itself a reputation as a leading contributor to the international research community<sup>166</sup> and that “in-person interactions are critical for building sustained, trusted research collaborations and for better understanding each country’s or region’s unique [science and technology] strengths and gaps.”<sup>166</sup>

Thus, presence at non-DoD sponsored conferences is critical for demonstrating DoD’s unique medical research capabilities, its successes, and the value it reaps the military and civilian communities, as well as building and strengthening collaborative research partnerships.

Further information on attribution of DHP medical research can be found in [Appendix E](#).

## 1.8 FINDINGS AND RECOMMENDATIONS

**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. 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.
- 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).
- 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.

**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.
- 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.
- 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:** 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.
- 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).
- 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.

**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.
- 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.
- 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:** 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.
- 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.

**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.

**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.

**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.
- 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.
  - 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:** 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.

**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:** 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. 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.

**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.
- 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.



# SUPPORTING APPENDICES

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## APPENDIX A. STRATEGIC ROLE OF MEDICAL RESEARCH IN THE DEPARTMENT OF DEFENSE

The Department of Defense (DoD) has historically made numerous contributions to the field of medical research, benefitting both military and civilian populations. The Institute of Medicine<sup>‡</sup> Committee on Health Research and the Privacy of Health Information stated, “research discoveries are central to achieving the goal of extending the quality of healthy lives.”<sup>4</sup> Such medical research discoveries are carried out in diverse settings throughout DoD, as highlighted in Figure 3. DoD’s historical research contributions are particularly valuable for the rapid response to emerging infectious diseases, such as Zika.<sup>183</sup>

**Figure 3.** DHP Medical Research Historical Accomplishments.<sup>184,185</sup>

- Development of the Japanese encephalitis vaccine at the Walter Reed Army Institute of Research
- Naval Health Research Center’s surveillance efforts for the H1N1 pandemic at Naval Medical Center San Diego

Adapted from U.S. Army, 2009 and Coffey, L., 2009.

The main objectives of Defense Health Program (DHP) medical research (research, development, test, and evaluation [RDT&E] and Clinical Investigation Programs [CIPs]) include optimizing health and performance of the total force; improving the quality of patient care in the Military Health System (MHS) through improved knowledge, practices, materiel, pharmaceuticals, and evidence-based treatment and guidelines; and maintaining a medical research portfolio response to the needs of the MHS.<sup>18</sup> DoD’s medical research can be specifically aimed at decreasing morbidity and mortality of warfighters, such as the Combat Casualty Care Research Program, or can be a collaborative effort between a university and a CIP to address general public health concerns.<sup>186</sup> DoD has its own graduate medical education programs, through which it supports the completion of scholarly activity as required by the Accreditation Council for Graduate Medical Education. The Accreditation Council for Graduate Medical Education states that residents’ curricula “must advance residents’ knowledge of the basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care.”<sup>152</sup> Therefore, DoD has a vested interest in research to advance military medicine, to improve care for its beneficiaries, and to train the next generation of physicians and DoD investigators. However, there are opportunities to improve research processes and enhance the productivity and quality of medical research in the Department.

### A.1 ROLE OF COMMAND

According to DoD Instruction 6000.08, “DHP-funded medical research and CIP are essential missions of the MHS.”<sup>18</sup> This requires that DoD’s health-related leadership across the Department, Services, and the Defense Health Agency (DHA) and commanders at every level make basic, clinical, and translational research a priority. However, despite being indicated as

<sup>‡</sup> Members of the National Academy of Sciences voted to change the name of the Institute of Medicine to the National Academy of Medicine effective July 1, 2015.



“essential missions of the MHS,”<sup>18</sup> during roundtable discussions, there was consistent concern about insufficient command attention to the conduct of research.

A wealth of literature is devoted to the importance of building a culture of research and the critical role of leadership.<sup>187-193</sup> In a 1996 Institute of Medicine report on military nursing research, the authors assert, “basic to the evolution of strong programs of military nursing research is the development of a culture deeply grounded in research and its use as a primary means for improving the military health care system.”<sup>194</sup> A 2014 Hanover Research report reviewed the published literature and recommended practices for developing a culture of research in higher education. The authors noted, “an institution’s culture of research is not simply a group of scholars who see the importance of research. A culture of research provides a supportive context in which research is uniformly expected, discussed, produced, and valued.”<sup>195</sup> Additionally, increased research productivity has been related to higher favorability of institutions<sup>196</sup> and has been cited as an important factor for the hiring and promotion of faculty members.<sup>187</sup> The 1996 Institute of Medicine report on military nursing research continues that “the creation of a research culture will facilitate a program of knowledge generation required to improve standards of military nursing practice and to improve the health of service members and their beneficiaries.”<sup>194</sup> Therefore, a culture of research positively affects institutions and investigators by encouraging scholarship, providing an environment for growth and study, facilitating continuous quality improvement, and promoting a problem-solving mentality that serves the institution and its mission.

In 2005, Bland et al tested the ability of a 2002 model, looking at variables influencing faculty research productivity to examine research productivity within a large medical school. Bland et al concluded that productivity is influenced by the interaction of individual, institutional, and leadership characteristics, and “it is the dynamic interplay of individual and institutional characteristics, supplemented with effective leadership, that determines the productivity of individuals and departments.”<sup>197</sup> Thus, while there is no singular strategy that alone produces a productive research environment, supportive leadership is always a key ingredient. Leadership must understand and appreciate the role and importance of research, support those who conduct research, both with resources and moral support, reward achievements, and ensure that research efforts and the workforce needed to support such efforts are sustained over time.

## A.2 SETTING THE DEFENSE HEALTH PROGRAM MEDICAL RESEARCH AGENDA: ROLES AND RESPONSIBILITIES

There are multiple sources and levels of strategic guidance concerning DHP medical research. The Department has several mechanisms for directing, coordinating, resourcing, and overseeing research activities. In addition, as will be discussed in [Appendix B](#), the Services have their own policies and programs for conducting and supporting research. With the passage of the National Defense Authorization Act for Fiscal Year (FY) 2017, however, there will soon be an evolution in the roles and responsibilities for the DHA and the military treatment facilities (MTFs), in particular.<sup>23</sup>



## ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

According to DoD Directive 5136.01, *Assistant Secretary of Defense for Health Affairs (ASD(HA))*, the ASD(HA) “develops policies, procedures, and standards that govern the management of DoD health and medical programs,” including medical research and development and clinical investigations.<sup>198</sup> DoD Instruction 6000.08 states that the ASD(HA) “develops and issues strategic guidance in coordination with the Assistant Secretary of Defense for Research and Engineering” in regard to military medical research, and “ [Office of the Secretary of Defense] and DoD Components will give priority to authorizing CIP and DHP funded research projects that are aligned with the strategic guidance from the ASD(HA).”<sup>§18</sup>

Capabilities Based Assessments, which are a Joint Capabilities Integration and Development System analytic process, are conducted in support of the Office of the ASD(HA) to identify and reassess capability gaps and requirements for DHP medical research.<sup>199</sup> Capabilities Based Assessments are conducted by portfolio or subject areas; for example, Global Health Engagement, Comprehensive Health Surveillance, Military Operational Medicine, or Clinical Rehabilitative Medicine.<sup>39</sup> These assessments are conducted periodically at the request of the ASD(HA); however, there is no fixed schedule.<sup>39</sup>

## ASSISTANT SECRETARY OF DEFENSE FOR RESEARCH & ENGINEERING

The Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (COI), established by the Assistant Secretary of Defense for Research and Engineering and co-chaired by the ASD(HA), “serves to facilitate coordination and prevent unnecessary duplication of effort within DoD biomedical research and development and associated enabling research areas.”<sup>32</sup> The ASBREM COI reviews “medical RDT&E program plans and accomplishments for quality, relevance, and responsiveness to military operational needs, the needs of the Military Health System, and the goals of Force Health Protection.”<sup>32</sup> It also reviews program plans and budgets in support of guidance relevant to National Security and missions and functions of DoD and provides coordination, recommendations, and support to DoD Executive Agents and other officials as requested or directed.<sup>32</sup> However, the ASBREM COI does not set research priorities. At the time of the publication of this report, the ASBREM COI was reported to be rechartering in order to include coordination of all medical RDT&E research, to include medical research under the purview of the ASD(HA) and the ASD(R&E). This appears to only include RDT&E-funded medical research and not the DHP operations and maintenance-funded CIPs.

The ASBREM COI is one of 17 COIs established in 2009 that “serve as an enduring structure to integrate technology efforts throughout the DoD S&T [science and technology] enterprise.”<sup>200</sup> Although the COIs cover a majority of DoD’s S&T investments, some Service-specific investments are not included.<sup>200</sup> These COIs are components of the Reliance 21 operational framework, which is the overarching framework for DoD S&T’s joint planning and coordination process.<sup>201</sup> As described in their operating principles, the Reliance 21 framework:

<sup>§</sup> Per DoD Instruction 6000.08, “DHP research is comprised of research, development, test, and evaluation (RDT&E) funds.”<sup>18</sup>



- describes how S&T leadership plans to coordinate, collaborate, and communicate strategic goals, objectives, and requirements across DoD;
- defines the technical framework and explains the expected output and outcome for all participants;
- provides DoD S&T workforce with a basic understanding of where their work fits in to the overall enterprise and builds awareness of the processes and tools available to them to foster collaboration with their peers;
- informs warfighters about how and when to connect with S&T communities to ensure that their needs are being addressed; and
- serves to improve the understanding of DoD S&T processes for external partners and stakeholders.<sup>202</sup>

## DEFENSE HEALTH AGENCY

The Director of the DHA “supports the conduct of studies and research activities to assist the ASD(HA) and others, as necessary, in support of their responsibilities and to support the management and implementation of health policies for the MHS developed by the ASD(HA).”<sup>24</sup> Additionally, the Director of the DHA “exercises management responsibility for shared services, functions, and activities in the MHS, including . . . medical research and development . . . as determined by the ASD(HA).”<sup>24</sup> The FY 2017 National Defense Authorization Act states that beginning October 2018, the Director of the DHA will be responsible for the administration and management of all MTFs, including budgetary matters, information technology, administrative policy and procedure, military medical construction, and other matters as deemed appropriate by the Secretary of Defense.<sup>23</sup> Given that the National Defense Authorization Act does not specifically address medical research, it is unclear how it will drive changes for the administration of research conducted at the MTFs.

On behalf of the ASD(HA) and the Director of the DHA, each FY, the Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight provides “policy direction for execution management of the . . . [DHP] Medical Research, Development, Test, and Evaluation (RDT&E) appropriation.”<sup>25</sup> The Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight requests quarterly reports on DHP RDT&E activities and provides a list of DHP RDT&E priorities for the FY, for example, acute and chronic pain management, combating antimicrobial resistance, or the National Research Action Plan to support the Executive Order “Improving Access to Mental Health Services for Veterans, Service Members, and Military Families.”<sup>25</sup> In the FY 2015 strategic guidance, the Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight also emphasized increased “data-sharing for research activities in concert with emerging government-wide efforts to increase access to the results of federally-funded scientific research,” including moving DHP RDT&E-supported activities onto the National Institutes of Health Research Portfolio Online Reporting Tools Expenditures and Results tool.<sup>25</sup> This move to National Institutes of Health Research Portfolio Online Reporting Tools Expenditures and Results tool is currently in progress (see [Section C.4](#), Visibility of Projects for Collaborative Medical Research).<sup>117</sup>



The Joint Program Committees (JPCs), which are DHA Research and Development Directorate advisory bodies composed of medical and military experts, also support the DHA Research and Development Director in the planning, programming, budgeting, and execution of DHP RDT&E research for a specific medical research task area, for example, medical simulation and information sciences (JPC-1).<sup>26-31</sup> JPC Working Group Leads support the JPC Chair “in the development of [planning, programming, and budgeting] recommendations to the DHA [Research, Development, and Acquisition]\*\* Director for the DHP RDT&E appropriation.”<sup>26-31</sup> The JPC Working Group Lead conducts gap analyses and provides recommendations for specific objectives in response to JPC program goals, as well as recommended topics for funding instruments “from prioritized and validated research gaps.”<sup>26-31</sup>

As noted in the JPC charters, “each appointed member of the JPC is responsible for supporting the processes that help refine research gaps and balance the portfolio of investment.”<sup>26-31</sup> Additionally, “members inform the JPC of relevant RDT&E efforts that are independently sponsored by the Services, Components, and other Federal Agencies that they represent.”<sup>26-31</sup> Members guarantee that the DHA Research and Development RDT&E programs:

- are aligned to capability gaps and requirements;
- can be integrated into and implemented by the MHS and the military Services and Components;
- effectively leverage and are not duplicative of other related RDT&E efforts within DoD and/or other Federal Agencies; and
- provide a balanced overall RDT&E program, including an appropriate balance between technology push and requirements pull.<sup>26-31</sup>

The JPCs advise U.S. Army Medical Research and Materiel Command’s Program Area Directorates, which provide strategic oversight of DHA Research and Development-funded research. The Congressionally Directed Medical Research Programs then works with the Program Area Directorates to execute a number of programs.<sup>11</sup> This combined effort leverages the Congressionally Directed Medical Research Programs’ s expertise in research program administration with the Program Area Directorates’ technical and strategic expertise for the advancement of the DHA Research and Development mission.<sup>11</sup>

## SERVICES

The Army, Navy, and Air Force each conduct Service-specific research that is not DHP-funded (e.g., line-funded). For example, the Air Force Office of Scientific Research “plans, coordinates, and executes the Air Force Research Laboratory’s basic research program in response to technical guidance from the [Air Force Research Laboratory] and requirements of the Air Force.”<sup>203</sup> Service-specific research commands that support the conduct of medical research, such as U.S. Army Medical Research and Materiel Command, Naval Medical Research Center, and Air Force Research Laboratory have command and control over research executed through their subordinate organizations. Although the Director of the DHA “exercises management

\*\* The Defense Health Agency Research, Development, and Acquisition Directorate was renamed the Research and Development Directorate in late 2016.



responsibility”<sup>24</sup> over medical research and development, the Services maintain command and control of research they execute.

### A.3 CHALLENGES FOR DEFENSE HEALTH PROGRAM MEDICAL RESEARCH PRIORITIZATION

Despite efforts to increase data sharing of DHP RDT&E research activities (discussed further in [Appendix C.4](#)), the Defense Health Board (DHB) frequently heard that it is difficult to locate a comprehensive summary of current medical research priorities, strategic guidance, or current activities. Further, there are multiple strategic drivers for DHP medical research, including the Capabilities Based Assessments; research priorities determined by the Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight and the JPCs; Executive initiatives; as well as Service Secretaries, Surgeons General, and Combatant Command priorities.<sup>36</sup> DoD institutions, including DHP medical research laboratories and MTFs, also provide mission and vision statements, some of which do not prioritize research. DoD’s RDT&E laboratories may have additional drivers of requirements, as well. For example, the Chemical and Biological Defense Program may drive research priorities at the U.S. Army Medical Research Institute of Chemical Defense, or laboratories conducting basic research may use In-House Laboratory Independent Research funds, which can also drive research requirements. Therefore, strategic guidance for medical research comes from various sources, which may not align.

Although DoD Instruction 6000.08 states that the “[Office of the Secretary of Defense] and DoD Components will give priority to authorizing CIP and DHP funded research projects that are aligned with strategic guidance from the ASD(HA),”<sup>18</sup> it is difficult to locate such strategic guidance for either CIP or DHP RDT&E funded DoD medical research. Additionally, DoD investigators are challenged to find a comprehensive list of current funding opportunities for DoD-funded medical research. For example, if an investigator were interested in intramural funding opportunities under a particular JPC, he or she would have to search the Congressionally Directed Medical Research Programs<sup>204,205</sup> and JPC websites.<sup>206-208</sup> In some cases, the JPC’s site links to Grants.gov for funding, the investigator must request access to the JPC site, or the link to subscribe to a JPC’s listserv for funding opportunities is difficult to locate, if one is available.

In addition to research conducted by DoD-sponsored investigators, DoD’s medical residents must complete scholarly activities as required by the Accreditation Council for Graduate Medical Education, which vary by specialty (to be discussed in further detail in [Appendix D.2](#)). For example, allergy and immunology residents “must design and conduct allergy and/or immunology research that is either laboratory-based, epidemiologic, continuous quality improvement, or clinical investigation-based.”<sup>209</sup> Scholarly activities may be carried out under DHP CIPs, along with other Graduate Health Sciences Education (e.g., Graduate Nursing Education, Graduate Dental Education).<sup>18</sup> However, it is unclear to what extent MHS or Service research priorities are made available to or used by trainees at various Graduate Health Sciences Education training programs to guide their selection of research topics. This is also true for mid-level and senior clinicians who aspire to conduct human subjects research outside of the context of the Graduate Health Sciences Education training programs.



Despite these barriers, there have been positive efforts to provide investigators with better support and guidance. For example, the Army has a newly stood up Clinical and Translational Research Program Office that will work to ensure alignment of the Army CIP portfolio with the objectives of the DHP as denoted in DoD Instruction 6000.08.<sup>59</sup> Another positive example is the DoD Hearing Center of Excellence, which sets and disseminates research priorities so investigators do not have to initiate research without strategic guidance. This center, along with the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, has recently been realigned under the DHA, which will help to provide strategic, coordinated direction for their research.

Additionally, as directed by the Office of the ASD(HA), since FY 2013 the Congressionally Directed Medical Research Programs has been the executing agent for the Clinical Research Intramural Initiative Program Announcement.<sup>131</sup> The goal of the Clinical Research Intramural Initiative Program Announcement is to provide research funding for DoD intramural investigators for clinical research. The clinical research funded through the Clinical Research Intramural Initiative must be performed within a DoD research site or MTF, and the research conducted is a topic of direct relevance to the MHS. Each FY, a research topic and priority areas are determined for the Clinical Research Intramural Initiative. For example, for FY 2016, the research topic was precision medicine research.<sup>131</sup> Finally, the DHA Research and Development Directorate will begin rolling out integrated program plans in 2017 to improve alignment of DHP RDT&E research funding to capability gaps.<sup>39</sup> Despite these positive efforts, it would be beneficial if DoD were to take a systematic, enterprise-wide review of its medical research activities and policies in order to develop a more coordinated and transparent framework for moving its medical research agenda forward.



## APPENDIX B. DEFENSE HEALTH PROGRAM MEDICAL RESEARCH OVERSIGHT AND EXECUTION

The Assistant Secretary of Defense for Health Affairs (ASD(HA)) exercises authority over all Defense Health Program (DHP) research and Clinical Investigation Programs (CIPs).<sup>18</sup> Department of Defense (DoD) policy also dictates that the Defense Health Agency (DHA) manage and execute the DHP appropriation as directed by the ASD(HA).<sup>24</sup>

### B.1 DEFENSE HEALTH PROGRAM RESEARCH, DEVELOPMENT, TEST, AND EVALUATION PROGRAM

The DHP Research, Development, Test, & Evaluation (RDT&E) program, previously known as the Defense Medical Research and Development Program, was established by the 2008 Guidance for the Development of the Force study and invests in military relevant materiel and non-materiel solutions.<sup>40</sup> The DHP RDT&E program is separate from the CIPs, which are DHP O&M-funded and led by the Services. Programmed funding for DHP RDT&E began in Fiscal Year (FY) 2010, and additional guidance has been provided in the form of joint requirements and Presidential direction since the publication of the Guidance for the Development of the Force study. For example, Executive initiatives, such as the Precision Medicine Initiative and the National Research Action Plan, are included in the DHP RDT&E portfolio.<sup>40</sup>

DHP RDT&E program funding consists of core funding (President's Budget) from the DHP RDT&E appropriation, as well as Congressional Special Interest funding. Program funds are designated by budget activities 6.1-6.7, such as basic research (6.1), advanced technology development (6.3), or operational system development (6.7).<sup>40</sup> In FY 2015, \$1.7 billion in DHP RDT&E medical research was enacted, which includes \$1.08 billion in Congressional Special Interest medical research.<sup>1</sup> RDT&E funds support intramural and extramural research and are available for obligation for two FYs. Intramural research includes research conducted at military treatment facilities (MTFs), DoD laboratories, or even collaborative projects. Extramural research can be conducted by other federal agencies, academia, or industry.<sup>41</sup>

Management, execution, and support of the DHP RDT&E research program are complex. Within the DHA, the Research and Development Directorate manages and executes the DHP RDT&E appropriation.<sup>42</sup> The Director of the DHA Research and Development Directorate also serves as the Deputy Director of U.S. Army Medical Research and Materiel Command (USAMRMC). Under USAMRMC, the Congressionally Directed Medical Research Programs (CDMRP) provides DHP RDT&E program execution management support for six core research program areas, each managed by a Joint Program Committee (JPC):

- Medical Simulation and Information Sciences (JPC-1)
- Military Infectious Diseases (JPC-2)
- Military Operational Medicine (JPC-5)
- Combat Casualty Care (JPC-6)
- Radiation Health Effects Research Program (JPC-7)
- Clinical and Rehabilitative Medicine (JPC-8)<sup>42</sup>



The CDMRP, in partnership with the JPCs, “supports development of program announcements, solicitation and review of applications, full life-cycle management of awards, as well as program evaluation and planning.”<sup>11</sup> The CDMRP will be discussed further in [Appendix B.3](#). The JPCs “support the DHA RDA Director in the [planning, programming, budgeting, and evaluation] oversight of RDT&E activities that support discovery and development of materiel, knowledge, and training solutions associated with medical capability gaps”<sup>26-31</sup> relevant to the six core research program areas. JPCs are DHA Research and Development advisory bodies composed of medical and military experts who provide funding recommendations and program management support for DHA Research and Development-funded research.<sup>11,26-31</sup>

Research is then executed through agents such as USAMRMC, Uniformed Services University of the Health Sciences (USUHS), Office of Naval Research, Air Force Office of Scientific Research, and the U.S. Navy Bureau of Medicine and Surgery, as well as academia, industry, and other government agencies.<sup>11</sup> Although the DHA Research and Development Directorate manages and executes the DHP RDT&E appropriation,<sup>42</sup> the Directorate currently does not have full financial visibility on the execution of these funds because of a lack of financial reporting below task areas (e.g., combat casualty care), inaccurate accounting mechanisms, and delays in reporting.<sup>39</sup> Further, the obligation of DHP RDT&E funds may be significantly delayed because of the inability to track execution. However, the DHA Research and Development Directorate is addressing this by coordinating with the Services to create work breakdown structures within their cost accounting systems and generate automatic quarterly reports of DHP RDT&E obligations and expenditures.<sup>39</sup>

## B.2 LINE-FUNDED MEDICAL RESEARCH

### ARMY

For the Army Medical Command, medical research is conducted at either Army MTFs or laboratories under the command of USAMRMC. MTF clinical investigations supporting Graduate Health Sciences Education will be discussed in [Appendix B.2](#). USAMRMC manages the federally appropriated Army core (President’s budget) and assigned Army and DHP Congressional Special Interest funding for medical research and development.<sup>41</sup> A majority of USAMRMC Congressional Special Interest funds are then executed through the CDMRP, U.S. Army Medical Materiel Development Activity, or the U.S. Army Medical Materiel Agency.<sup>41</sup>

USAMRMC manages and executes Army medical research in the six core research program areas noted above (e.g., military infectious diseases). Army medical research conducted using either Army core or DHP RDT&E funds can be executed through USAMRMC component laboratories and research institutes, such as the U.S. Army Institute for Surgical Research; USAMRMC subordinate laboratories, such as the U.S. Army Medical Research Institute of Infectious Diseases; or special foreign activities, such as the U.S. Army Medical Research Unit – Kenya component of the Walter Reed Army Institute of Research (Figure 4).<sup>41</sup>



## NAVY

Navy medical research is divided between Science and Technology (RDT&E budget activities 6.1-6.3) and Advanced Development (RDT&E budget activities 6.4-6.7). The Office of Naval Research is the Navy authority for Science and Technology programs and “coordinates, executes, and promotes the Science and Technology programs of the Navy and Marine Corps.”<sup>41</sup> A majority of the Navy’s medical research is managed by the Office of Naval Research’s Warfighter Performance Department under the direction of the Force Health Protection pillar of the Future Naval Capability program. The U.S. Navy Bureau of Medicine and Surgery oversees a majority of Navy Advanced Development medical research.<sup>41</sup>

For Navy medical RDT&E research, the Naval Medical Research Center is “both the Headquarters for seven subordinate RDT&E laboratories and a major research laboratory.”<sup>210††</sup> Navy laboratories are located in the continental United States and overseas, such as the Naval Health Research Center in San Diego, California or the Naval Medical Research Center – Asia in Singapore (Figure 4).<sup>210</sup> Navy medical research is also conducted within the Navy systems commands under sponsorship of the Assistant Secretary of the Navy and Marine Corps for Research Development and Acquisition, as well as the Naval Postgraduate School and the Naval War College, to a smaller extent.<sup>41</sup> Navy’s medical researchers investigate infectious diseases; biological warfare detection and defense; combat casualty care; environment health concerns; bone marrow research and registry; aerospace and undersea medicine; medical modeling, simulation and operational mission support; and epidemiology and behavioral sciences.<sup>210</sup>

## AIR FORCE

The Air Force Medical Support Agency Directorate for Research and Acquisition oversees Air Force medical research funding. A majority of Air Force medical research is then executed through two platforms, the 59th Medical Wing at Joint Base San Antonio and the Air Force Research Laboratory’s 711th Human Performance Wing at Wright-Patterson Air Force Base (Figure 4).<sup>41</sup>

The mission of the 59th Medical Wing Office of the Chief Scientist, Science and Technology, is to “conduct clinical studies and translational research and apply knowledge gained to enhance performance, protect the force, advance medical care and capabilities across the global health system, and train future medical leaders.”<sup>133</sup> This office supports clinical researchers at 70 sites and includes a Trauma and Clinical Care Research Program, clinical investigations and research support, Diagnostics and Therapeutics Program, Center for Advanced Molecular Detection, Nursing Research Division, Air Force Post Graduate Dental School and Clinic, and Dental Research.<sup>133</sup> The Air Force Research Laboratory’s 711th Human Performance Wing includes the Airman Systems Directorate, the U.S. Air Force School of Aerospace Medicine, and the Human Systems Integration Directorate,<sup>211</sup> and its “mission is to advance human performance in air, space, and cyberspace through research, education, and consultation.”<sup>212</sup>

<sup>††</sup>In August 2015, Navy Medicine West assumed cognizance over the U.S. Navy research and development enterprise headquartered at NMRC.



**Figure 4.** DoD Medical Laboratories.



Adapted from U.S. Army Medical Research and Materiel Command, Naval Medical Research Center, and Air Force Research Laboratory.

### B.3 UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

USUHS, a DoD university, reports to the ASD(HA).<sup>43</sup> The Office of the Vice President for Research facilitates, promotes, and oversees all of the University’s research activities. This office supports faculty investigators, the University, and the approximately 80 funding organizations that support USUHS’s research activities.<sup>44</sup> Medical research and development is funded intramurally using DHP RDT&E funds, or it can be funded using extramural sources, such as grants through the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF).<sup>213</sup> Medical research at USUHS can be conducted through the Armed Forces Radiobiology Research Institute,<sup>48</sup> Biomedical Instrumentation Center,<sup>49</sup> Center for Laboratory Animal Medicine,<sup>50</sup> Tri-Service Nursing Research Program,<sup>214</sup> and Center for Neuroscience and Regenerative Medicine.<sup>66</sup> USUHS has also recently programmed DHP RDT&E funding for a new health services research program and is expected to begin requests for proposals in one to two years. This program is filling a gap noted in the 2014 *Military Health System Review: Final Report to the Secretary of Defense*, which stated that “Although the [Military Health System] has a wealth of data, the ability to analyze those data and use the results to guide decision making in quality and patient safety is nascent.”<sup>215</sup>



HJF is authorized by Congress to support research activities at USUHS.<sup>46</sup> Per Title 10, U.S. Code, Section 178:

It shall be the purpose of the Foundation (1) to carry out medical research and education projects under cooperative arrangements with the Uniformed Services University of the Health Sciences, (2) to serve as a focus for the interchange between military and civilian medical personnel, and (3) to encourage the participation of the medical, dental, nursing, veterinary, and other biomedical sciences in the work of the Foundation for the mutual benefit of military and civilian medicine.<sup>216</sup>

HJF supports medical research at USUHS's School of Medicine, School of Nursing, Postgraduate Dental College, and the Armed Forces Radiobiological Research Institute.<sup>47</sup> HJF facilitates the provision of staffing, program and financial management, and administrative and logistical support. According to HJF, in 2014, it managed approximately 400 grants, contracts, and cooperative agreements on behalf of USUHS and employed about 400 personnel on the USUHS campus; about 500 HJF personnel are employed at off-site USUHS research programs.<sup>47</sup>

#### B.4 CLINICAL INVESTIGATION PROGRAMS

In contrast to the DHP RDT&E program, CIPs are managed separately by each Military Department (Army, Navy, and Air Force),<sup>\*\*</sup> given their Title 10 authority to man, train, and equip,<sup>55-57</sup> along with the DHA's National Capital Region Medical Directorate (NCR MD) and USUHS. Therefore, there is no central management of the CIPs. The CIPs support Graduate Health Sciences Education (e.g., Graduate Medical Education[GME]) and other allied health programs of the Services and also promote professional standing and accreditation of health education and training programs within the Military Health System.<sup>18</sup> CIP activities are carried out at MTFs or dental/medical clinics. Under the purview of the Under Secretary of Defense for Personnel and Readiness, the Research Regulatory Oversight Office oversees "intramural and extramural research activities involving humans and animals to ensure compliance with legal and ethical requirements," including clinical investigations conducted in the Military Health System.<sup>51</sup> Each of the CIP representatives of the Military Departments, NCR MD, and USUHS provide an annual report to the ASD(HA) on their CIP activities.<sup>18</sup> However, this is not a report that is readily available to the public.

In contrast to DHP RDT&E funds being designated by budget activities, the CIPs primarily rely on O&M funding, which is designated by Budget Activity Groups: In-House Care; Private Sector Care; Consolidated Health Support; Information Management; Management Activities; Education and Training; Base Operations/Communications; and Facilities Sustainment, Restoration, and Modernization.<sup>1</sup> CIP funding is included in the In-House Care Budget Activity Group for the Navy and the Consolidated Health Support Budget Activity Group for the Army

<sup>\*\*</sup> For the Army, regional Department of Clinical Investigations oversee and approve clinical research. For the Navy, research at MTFs is administered by the regional medical centers' Clinical Investigation Department and approved by the local Command.<sup>41</sup> The Air Force Medical Service establishes Clinical Investigation Facilities "at MTFs to conduct scientific studies with the potential to improve patient treatment, diagnosis, or well-being."<sup>41</sup>



and Air Force. In contrast to DHP RDT&E funds, DHP O&M funds are only available for obligation for one FY.

DoD Instruction 6000.08 states, “CIP may receive DHP RDT&E funding for [Clinical Investigations] on health problems encountered by DoD eligible beneficiaries if such investigations are in support of human clinical trials in the DHP RDT&E research areas.”<sup>18</sup> Additionally, “CIP may receive funding on a case by case basis from non-DHP research funds in accordance with applicable federal laws and written agreements with the non-DHP sponsor.”<sup>18</sup> However, during roundtable discussions with DoD investigators, it was revealed to the Defense Health Board (DHB) that many MTFs are hesitant to accept DHP RDT&E funds. For example, MTF budget analysts may be unfamiliar with RDT&E funds and they may be lumped into the MTF’s accounting management system (e.g., Army’s General Fund Enterprise Business System), leading to difficulties locating, itemizing, and maintaining visibility of the funds.

For FY 2015, the total CIP funding for the Army, Navy, and Air Force totaled just over \$46.2 million, which includes intramural O&M funds, intramural RDT&E funds, and extramural funds. This includes 323 support personnel, 316 trainee programs, 4,226 trainees, and 2,636 faculty (Table 1).

**Table 1.** FY 2015 CIP Funding, Personnel, and Trainees<sup>146</sup>

	Army	Navy	Air Force	Total
Total Funding (Intramural O&M, Intramural RDT&E, Extramural)	\$29,336,730	\$9,700,000	\$7,226,080	<b>\$46,262,810</b>
Full Time Equivalent Employees (compliance and research support; Military/Civilian/Contractors)	138.5	65	119.4	<b>323</b>
Trainee Programs (GME, Graduate Dental Education, Graduate Nursing Education, Allied Health Education)	184	51	81	<b>316</b>
Trainees	1787	705	1734	<b>4226</b>
Faculty	1368	866	402	<b>2636</b>

From DHA Research and Development Directorate, 2016.

## ARMY

The Army Surgeon General prepares policies and regulations related to Army CIPs. Within Army medical centers, the commander is responsible for all clinical investigations conducted. The medical center commander also must “organize a clinical investigation support system within a separate hospital organizational structure to implement the CIP” and “appoint a clinical investigation committee, a [human use committee], and an [animal use committee].”<sup>58</sup>

Commanders of MTFs or dental treatment facilities are directed to use their regional medical center’s Department of Clinical Investigation (DCI) for clinical investigation support, or they



may seek approval from headquarters (U.S. Army Medical Command) for clinical investigation support.<sup>58</sup>

Army Regulation 40-38 states that CIPs are to be funded with procurement and O&M funds, but USAMRMC may provide RDT&E funds to MTFs/dental treatment facilities to support investigations related to one of their “designated research areas and one or more line items comprising USAMRDC’s available RDTE appropriation.”<sup>58</sup> CIPs may also be conducted using grants from federal agencies (e.g., National Institutes of Health) or tax-exempt “corporations, foundations, funds, or educational institutions operated primarily for scientific, literary, or educational purposes.”<sup>58</sup>

The Clinical Investigations Regulatory Office, previously a subordinate office of USAMRMC Office of Research Protections, recently transitioned to the Clinical and Translational Research Program Office. The Clinical and Translational Research Program Office, stood up in June 2016, manages the Army CIPs on behalf of the U.S. Army Medical Command under DoD Instruction 6000.08; facilitates assistance to investigators, scientific review of protocols, technology transfer activities, and handling of research-related funds; and facilitate delivery and utilization of clinical, scientific, and administrative research support services. Further, the Clinical and Translational Research Program Office liaises with the Navy and Air Force CIPs and the DHA Research and Development Directorate. The Army has six regional DCIs that support the CIPs, located at the Madigan Army Medical Center (AMC), Brooke AMC, William Beaumont AMC, Tripler AMC, Dwight D. Eisenhower AMC, and Womack AMC (Figure 5).

Army’s regional DCIs supports all clinical research that occurs in their respective and nearby MTFs; DCIs do not support clinical research activities conducted at USAMRMC subordinate laboratories. DCIs also support the IRBs at Army MTFs.<sup>41</sup> After approval by the DCI, clinical research projects have a second-tier review at USAMRMC Office of Research Protections’ Human Research Protections Office.<sup>41</sup> Per DoD Instruction 3216.02, “research involving human subjects covered under this Instruction shall also comply with applicable Federal and State laws and regulations.”<sup>77</sup> For the Army, all proposals and protocols funded by USAMRMC must be reviewed by the Human Research Protections Office to ensure these requirements are met.<sup>41</sup>

## NAVY

The Navy Surgeon General, also the Chief of the U.S. Navy Bureau of Medicine and Surgery, is responsible for establishing Navy CIP policy and maintaining oversight.<sup>61</sup> On behalf of the Navy Surgeon General, the Special Assistant for Clinical Research and Director, CIP, is the program manager for Navy CIPs. Commanders of Navy Medical Regions oversee clinical investigation activities within their region, and commanders of Navy MTFs oversee clinical investigations within their Command. Within MTFs, Directors of Clinical Investigation Departments (CIDs) act as program managers and are a central point of contact for Navy investigators.<sup>61</sup>



U.S. Navy Bureau of Medicine and Surgery's CIDs are located at Naval Medical Center Portsmouth for Navy Medicine East and Naval Medical Center San Diego for Navy Medicine West (Figure 5).<sup>41</sup> These CIDs provide support to research efforts of the medical staff, as well as administrative support for the Navy Medicine East and Navy Medicine West regional IRBs. The CIDs support MTFs with or without GME training programs. Clinical research leadership is also present at smaller MTFs with GME programs.<sup>52</sup> All levels of research review and determinations are made by CIDs or at the respective Navy research and development laboratory with research administrative support. The Department of the Navy Human Research Protection Program, similar to the Army's Human Research Protections Office, ensures compliance with federal and local laws and regulations related to human subjects research. Navy MTF or research and development laboratory commanders then provide final approval of research projects.<sup>41</sup>

## AIR FORCE

Similar to the Army and Navy, the Air Force Surgeon General is responsible for Air Force clinical investigations under a program called the Clinical Investigation and Human Use Program (CIHUP). The major command surgeon and installation commander are responsible for "CIHUP support and program compliance oversight for all CIHUP sites," and the "MTF Commander and Air Force Laboratory Director are responsible for implementing the CIHUP."<sup>62</sup> Per Air Force Policy Directive 40-4:

The Air Force will establish a Clinical Investigation and Human Use Program (CIHUP) in human-use laboratories, Clinical Investigation Facilities (CIF) and Medical Treatment Facilities (MTF) to conduct scientific studies in support of Air Force aeronautical and or aeromedical missions.

- 2.1. Human-Use Program Laboratories will be used to conduct research, development, test, and evaluation (RDT&E) studies that involve human subjects.
- 2.2. The Air Force Medical Service will establish CIFs at MTFs to conduct scientific studies with the potential to improve patient treatment, diagnosis, or well-being.<sup>62</sup>

Currently, the Air Force has seven CIFs located at: 60th Medical Group, David Grant Medical Center; 81st Medical Group, Keesler Medical Center; 59th Clinical Research Division; 88th Medical Group, Wright-Patterson Medical Center; 99th Medical Group, Mike O'Callaghan Federal Medical Center; U.S. Air Force School of Aerospace Medicine; and U.S. Air Force Academy Life Science Research Center (Figure 5).<sup>41</sup> The CIFs in the Air Force support all research efforts within the MTF where a CIF is located, as well as GME programs. Before any clinical research is conducted, the Air Force Research Oversight and Compliance Division and their designated human research protection officials provide regulatory reviews on behalf of the Air Force.<sup>41</sup>



## NATIONAL CAPITAL REGION MEDICAL DIRECTORATE

The DHA was established October 1, 2013 as part of an effort to streamline health care among the Army, Navy, and Air Force medical departments.<sup>217</sup> The DHA also “supports the delivery of integrated, affordable and high quality health services to Military Health System beneficiaries.”<sup>218</sup> The DHA operates under the authority of the ASD(HA) and the Under Secretary of Defense for Personnel and Readiness. The DHA’s NCR MD “exercises authority, direction, and control” over seven dental, health, and medical centers, including Walter Reed National Military Medical Center (WRNMMC), Fort Belvoir Community Hospital, and the Joint Pathology Center (Figure 5).<sup>63</sup>

For the NCR MD, the Department of Research Programs at WRNMMC supports investigators at WRNMMC, Fort Belvoir Community Hospital, and the Joint Pathology Center to “facilitate research and ensure that all regulatory standards are met.”<sup>64</sup> The Department of Research Programs has staff dedicated to research development, regulatory oversight, and compliance. As of 2013, it was estimated that 33 percent of medical research protocols approved for execution at all DoD MTFs were conducted within the NCR MD.<sup>41</sup>

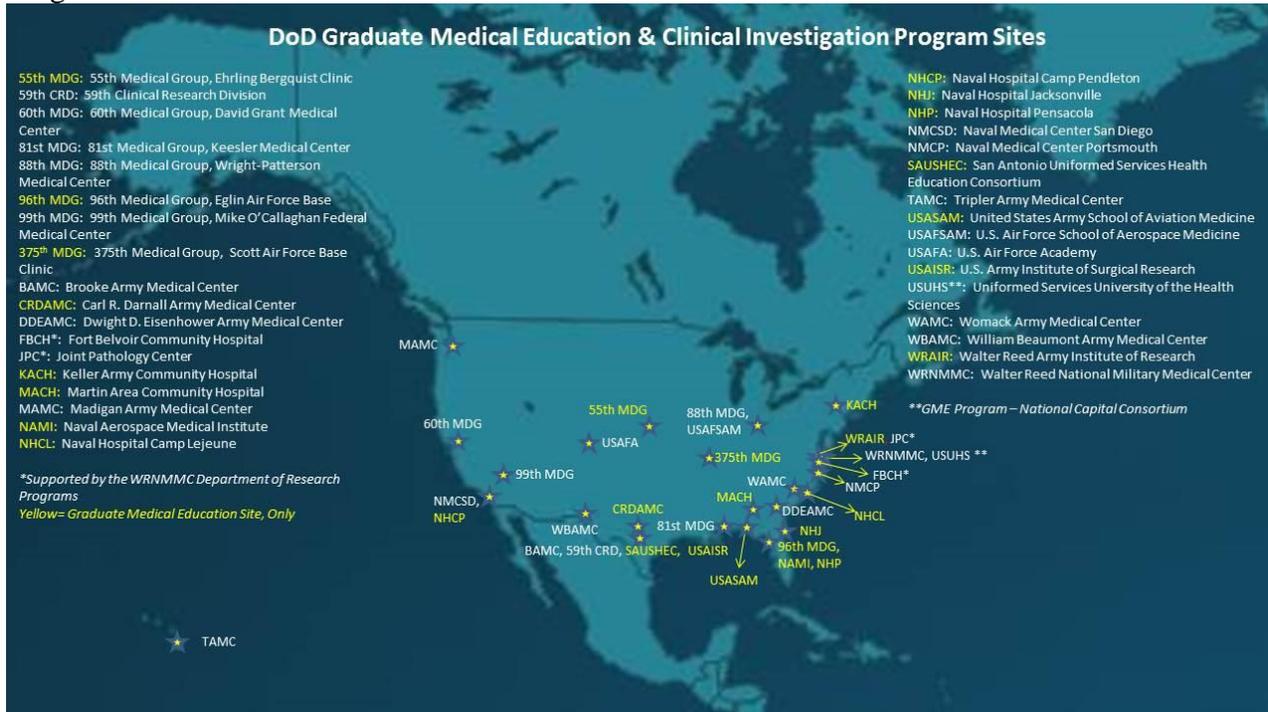
## UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

As stated previously, the Office of the Vice President for Research oversees all research activities at USUHS. USUHS provides many opportunities for clinical investigations, such as through its Clinical Research Unit. This unit, located in an outpatient research center, provides the requisite services, support, and infrastructure for clinical researchers from USUHS and WRNMMC.<sup>65</sup> Other research opportunities are available through USUHS’ various centers and programs, such as the Center for Neuroscience and Regenerative Medicine,<sup>66</sup> the Infectious Disease Clinical Research Program,<sup>219</sup> or the Collaborative Health Initiative Research Program.<sup>68</sup>

As previously noted in [Appendix B.1](#), HJF is authorized by Congress to support research at USUHS. As DHP O&M funds are only available for the obligation of one FY, it was briefed to the DHB that non-profits, such as HJF, have been useful for facilitating the management of DHP O&M funds and thus providing the needed flexibility to expend funds past one FY. This has been particularly useful for DoD’s multi-site clinical studies.



**Figure 5.** DoD Graduate Medical Education and Clinical Investigation Program Sites



From U.S. Army, U.S. Navy, and U.S. Air Force Clinical Investigation Programs and Defense Health Agency Education and Training Directorate.

### B.5 CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

In response to lobbying patient advocacy groups, 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.”<sup>69</sup> CDMRP, located within USAMRMC, is a “global funding organization for cancer research, military medical research, and other disease- and injury-specific research” and “represents a unique partnership among the U.S. Congress, the military, and public.”<sup>11</sup> CDMRP currently has 28 funded research programs, varying from the Duchenne Muscular Dystrophy Research Program to the Psychological Health/Traumatic Brain Injury Program (Table 2).<sup>70</sup>



**Table 2.** Currently Funded CDMRP Research Programs

<ul style="list-style-type: none"> <li>• Alcohol and Substance Abuse Disorders</li> <li>• Amyotrophic Lateral Sclerosis</li> <li>• Autism</li> <li>• Bone Marrow Failure</li> <li>• Breast Cancer</li> <li>• Defense Medical Research and Development</li> <li>• Duchenne Muscular Dystrophy</li> <li>• Epilepsy</li> <li>• Gulf War Illness</li> <li>• Joint Warfighter Medical</li> <li>• Lung Cancer</li> <li>• Military Burn</li> <li>• Multiple Sclerosis</li> <li>• Neurofibromatosis</li> </ul>	<ul style="list-style-type: none"> <li>• Orthotics and Prosthetics Outcomes</li> <li>• Ovarian Cancer</li> <li>• Parkinson's</li> <li>• Peer Reviewed Alzheimer's</li> <li>• Peer Reviewed Cancer</li> <li>• Peer Reviewed Medical</li> <li>• Peer Reviewed Orthopaedic</li> <li>• Prostate Cancer</li> <li>• Psychological Health/Traumatic Brain Injury</li> <li>• Reconstructive Transplant Research</li> <li>• Spinal Cord Injury</li> <li>• Tick-Borne Disease</li> <li>• Tuberos Sclerosis Complex</li> <li>• Vision</li> </ul>
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From CDMRP, 2015.

Since FY 1992, CDMRP has managed over \$9.7 billion in appropriations.<sup>11</sup> Funding for the programs is “a direct response to the needs of Service Members and their families, research communities, and the public at large.”<sup>11</sup> Unlike other programs, which submit a multi-year budget request to Congress in the form of the President’s Budget, funding for CDMRP is not included in DoD’s requested budget as “dollars for the CDMRP are not considered part of the DoD’s core mission.”<sup>71</sup> Therefore, “the dollars to fund CDMRP are added every year during the budget approval cycle by members of the House or Senate, in response to requests by consumer advocates and disease survivors.”<sup>71</sup> As such, CDMRP’s funded research programs may vary annually.

The National Academies of Sciences, Engineering, and Medicine released a report in November 2016 detailing their evaluation of CDMRP’s review processes.<sup>220</sup> The National Academies ultimately recommended that CDMRP develop strategic plans for each of their 28 research programs; have more formal coordination with other U.S. government agencies, including the National Institutes of Health and the Department of Veterans Affairs; improve transparency of its review processes; and improve standardization of its business practices.<sup>220</sup>



## APPENDIX C. INFRASTRUCTURE FOR DEFENSE HEALTH PROGRAM MEDICAL RESEARCH

Beyond the basic management and execution of medical research—as described in [Appendix B](#)—other infrastructure is critical to supporting the Department’s medical research mission. How one interprets the term “infrastructure” may have different implications, particularly in the context of research, which might have a wide range of foci and aims. For example, a 2011 Institute of Medicine report on comparative effectiveness research stated, “key infrastructure for a learning health system will encompass three core elements: data networks, methods, and workforce.”<sup>221</sup> A 2012 Institute of Medicine report on the clinical trials enterprise indicated that “the clinical trials infrastructure refers to the necessary resources (human capital, financial support, patient participants, information systems, regulatory pathways, and institutional commitment) and the manner in which they are organized and brought together to conduct a clinical trial.”<sup>222</sup> The European Commission defines research infrastructure as “facilities, resources and related services used by the scientific community to conduct top-level research in their respective fields.”<sup>223</sup> In Department of Defense (DoD) Instruction (DoDI) 6000.08, infrastructure support is defined as:

Support for Institutional Review Board [IRB] and Institutional Animal Care and Use Committee functions, research support, statistical support, grant writing assistance, funds for research related to maintaining accredited training programs, and other funds associated with maintaining research in the [Clinical Investigation Programs].

These examples demonstrate that the unique elements of an optimal medical research infrastructure may vary. The Defense Health Board (DHB) has thus focused its review on a few common elements of research infrastructure necessary for the Defense Health Program (DHP) medical research enterprise, such as regulatory support (e.g., IRBs) ([Appendices C.1-C.3](#)), collaborative research ([Appendix C.4](#)), technology transfer support ([Appendix C.5](#)), and personnel ([Appendix C.6](#)). [Appendix D](#) will discuss the challenges and opportunities related to professional development of DoD investigators.

Assessments of research infrastructure have long emphasized the need for stability and integration. For example, a 1996 Institute of Medicine report on military nursing research stated, “research programs benefit from a stable infrastructure for the setting and reviewing of priorities, administration of grants, development of information systems, consultation, and other services and activities.”<sup>194</sup> The 2012 Institute of Medicine report on the clinical trials enterprise also notes, “A broad-based, sustainable infrastructure could support multiple types of clinical trials in different settings.”<sup>222</sup> Further, Mann and Hess comment that for medical centers to “achieve a more integrated operational-research agenda,” they should “create the governance and organizational infrastructure that allows hybridization of research and operational goals, incentives, and resources.”<sup>224</sup> Therefore, stable infrastructure that facilitates all aspects of the research enterprise is necessary for the successful execution of medical research in DoD.

However, challenges associated with the lack of supportive research infrastructure in DoD were noted throughout conversations the DHB had with active duty and civilian investigators and have been noted in past reports. For example, a 2011 Center for Strategic and International Studies



report on DoD’s overseas medical research laboratories found that these “laboratories remain under-resourced, both in funding and personnel.”<sup>14</sup> In a 2016 article on military IRBs, the authors state “military IRBs review numerous protocols from clinicians interested in conducting research without funding and often without an independent science review.”<sup>72</sup> Further, the DHB was informed of past efforts within the Department to mitigate the challenges associated with medical research, including the lack of adequate research infrastructure. Despite these efforts, it was stated to the DHB that research infrastructure challenges are prevalent across the military medical research enterprise, particularly for clinical investigations. Accordingly, research infrastructure is crucial for the day-to-day operations of medical research in DoD. Without proper staffing, research coordination and administrative support, facilities, and sufficient resourcing, DoD investigators are left to navigate the intricate medical research regulatory pathways and processes alone. This can result in wasted time, inefficiencies, irregular policies and procedures, and missed opportunities to advance DoD’s research mission.

### C.1 DEPARTMENT OF DEFENSE & SERVICE-SPECIFIC POLICIES, ROLES, RESPONSIBILITIES, AND INFRASTRUCTURE SUPPORT PROVIDED FOR HUMAN SUBJECTS RESEARCH

A number of federal regulations govern research involving human subjects. The Department of Health and Human Services regulations, 45 Code of Federal Regulations (CFR) part 46, include four subparts: A, B, C, and D; subpart A is frequently referred to as the “[Common Rule](#),” and subparts B-D provide additional protections for vulnerable populations.<sup>74</sup> The Federal Policy for the Protection of Human Subjects, also known as the Common Rule, was published in 1991 and codified in separate regulations by 15 federal departments and agencies, including DoD.<sup>74</sup> The Common Rule describes basic requirements for IRB composition, review criteria, and operations; obtaining and documenting informed consent; and obtaining Assurances of Compliance with the regulations for research covered by the policy.<sup>74</sup> Each federal department and agency adopts the identical language of the Common Rule,<sup>74</sup> and DoD’s equivalent to the Common Rule is 32 CFR part 219. The U.S. Food and Drug Administration also has regulations codified in 21 CFR part 50 for the protection of human subjects, and IRB requirements are also prescribed in 21 CFR part 56.<sup>41</sup> The U.S. Food and Drug Administration regulations differ somewhat from the Common Rule.

Human subjects research conducted or supported by DoD is governed by 32 CFR part 219, as well as 10 U.S. Code section 980, *Limitation on Use of Humans as Experimental Subjects*.<sup>76</sup> The Assistant Secretary of Defense for Research and Engineering is the principal liaison for research involving human subjects conducted or supported by DoD and provides guidance and procedures necessary to carry out human subject research through DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*.<sup>77</sup> The Assistant Secretary of Defense for Research and Engineering also has the authority to “exercise the authorities of the Head of the Department” identified in the Common Rule, and “establish a process to oversee the DoD Components’ implementation of their respective Component human research protection program (HRPP) management plan and compliance with this Instruction,” among other responsibilities.<sup>77</sup>



The Assistant Secretary of Defense for Research and Engineering also consults with the Assistant Secretary of Defense for Health Affairs for medical research involving human subjects. The Assistant Secretary of Defense for Health Affairs advises the Assistant Secretary of Defense for Research and Engineering on matters related to the participation of human subjects in research, especially regarding medical safety, bioethics, and standards of professional health care and conduct, and represents DoD on matters relating to implementation of Food and Drug Administration regulatory requirements.<sup>77</sup> Additionally, each of the Services has their own policy to implement DoDI 3216.02.<sup>62,78-81</sup>

## ARMY

In addition to federal and local requirements, Army's human subjects research is governed by three Service-specific regulations:

- Army Regulation 40-7, *Use of U.S. Food and Drug Administration-Regulated Investigational Products in Humans Including Schedule I Controlled Substances*;<sup>225</sup>
- Army Regulation 70-25, *Use of Volunteers as Subjects of Research*;<sup>78</sup> and
- Army Regulation 40-38, *Clinical Investigation Program*.<sup>58</sup>

A number of organizations are responsible for the oversight of research involving human subjects sponsored or conducted by the Army. For example, U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP):

- ensures that USAMRMC-conducted, -contracted, -sponsored, -supported, or -managed research and USAMRMC investigations involving human subjects, human anatomical substances, or animals are conducted in accordance with federal, DoD, Army, USAMRMC, and international regulatory requirements;
- provides guidance regarding USAMRMC human subjects protection and animal welfare policies and procedures;
- develops educational activities for persons conducting or managing research; and
- implements an active compliance oversight program.<sup>82</sup>

USAMRMC ORP has three subordinate offices: Human Research Protection Office (HRPO), IRB Office, and Animal Care and Use Review Office.<sup>82</sup> The ORP HRPO is the principal advisor to USAMRMC for human subjects protection, and developments and implements human subjects policies and regulations.<sup>83</sup> On behalf of USAMRMC, the ORP HRPO also reviews and approves intramural and extramural human subjects protocols and conducts human subjects protection site visits.<sup>83</sup> USAMRMC-funded human subjects research must be approved by the ORP before funds are used to support the investigation.<sup>41</sup>

The ORP HRPO assigns a Human Subjects Protection Scientist to review the individual(s), institution(s), and the nature of their involvement for a proposed investigation involving human subjects.<sup>41</sup> To receive approval, a protocol must receive administrative, scientific, and IRB reviews. Scientific review is required before IRB review; however, some Army Departments of Clinical Investigation conduct the scientific review and IRB review concurrently.<sup>41</sup> As noted in [Appendix B.2](#), Army regional Departments of Clinical Investigation support the IRBs at Army military treatment facilities (MTFs). USAMRMC has its own IRB that is supported by the IRB Office, which is responsible for "IRB review, approval and oversight for human research



conducted by scientists assigned to . . . USAMRMC; at select USAMRMC subordinate Institutes and Laboratories; at select non-USAMRMC DOD institutions.”<sup>84</sup>

The Army also has an Army HRPO, which assesses and approves Army HRPPs; develops and disseminates Army regulations, policy, and guidance related to human subjects research; and ensures regulatory compliance, such as FDA and Health Information Portability and Accountability Act requirements.<sup>85</sup> The Army HRPO also negotiates new DoD Assurances and oversees the renewal of existing Assurances for all Army institutions, and provides headquarters-level administrative review.<sup>85</sup>

As noted in [Appendix B.2](#), the newly stood up Clinical and Translational Research Program Office manages the Army Clinical Investigation Programs. This new office reports to the provisional U.S. Army Medical Command Assistant Surgeon General/Deputy Chief of Staff for Quality and Safety, and will:

- serve as the federal laboratory for technology transfer activities, including administrative support and signature authority for cooperative research and development agreements (CRADAs) and other technology transfer agreements on behalf U.S. Army Medical Command organizations lacking their own federal laboratory authority;
- ensure efficiency of the entire research process, from protocol design through institutional and/or regulatory approval to protocol completion;
- ensure sufficient quality and quantity of scholarly products resulting from clinical research, including publications, presentations, and funding awards;
- facilitate, through the Departments of Clinical Investigation, efficient assistance to investigators, scientific review of protocols, technology transfer activities, and handling of research-related funds; and
- facilitate, through the Departments of Clinical Investigation, the efficient delivery and utilization of clinical, scientific, and administrative research support services.

## NAVY

The Navy follows a number of instructions related to the conduct of human subjects research, including:

- Secretary of the Navy Instruction 3900.39D, *Human Research Protection Program*;<sup>§§79</sup>
- Office of Naval Research Instruction 3900.34B, *Protection of Human Subjects*;<sup>80</sup>
- U.S. Navy Bureau of Medicine and Surgery Instruction 6710.69, *Use of Investigational Agents in Humans*;<sup>226</sup> and
- U.S. Navy Bureau of Medicine and Surgery Instruction 6000.12B, *Clinical Investigation Program and Other Research Activities Supporting Graduate Medical Education, Graduate Dental Education, and Graduate Health Science Professional Education*.<sup>61</sup>

The Department of the Navy’s HRPP is located in the Navy Surgeon General’s Office and develops and implements Navy policies and procedures for the protection of human research

<sup>§§</sup> The Marine Corps also has Marine Corps Order 3900.18, *Human Research Protection Program (HRPP)*.



subjects.<sup>86</sup> Amongst its numerous functions, the Department of Navy HRPP reviews and approves DoD/Department of Navy Assurances; monitors and oversees human research protocols through headquarters-level administrative review processes; and supports the review and approval of research protocols, as needed.<sup>86</sup> As noted in [Appendix B.2](#), research review and determinations are either provided by Clinical Investigation Departments, located at Naval Medical Center Portsmouth and Naval Medicine Center San Diego, or by Navy research laboratories with research administrative support. Commanders of these institutions provide final approval. Scientific review must be conducted before IRB review; however, these procedures may vary among Navy commands.<sup>41</sup>

The Navy's Clinical Investigation Departments provide various elements of research infrastructure support for its investigators. For example, Naval Medical Center San Diego's Clinical Investigation Department has a biostatistician, medical editor, veterinarian, clinical research coordinators, budget analyst, and an Office of Research and Technology Applications, as well as research compliance, research administration (IRB and [Institutional Animal Care and Use Committee (IACUC)]), and research facilitation and education.<sup>227</sup> The Clinical Investigation Department at Naval Medical Center San Diego also has core scientific laboratories and has developed a Research Methods Training Program,<sup>132</sup> which will be further discussed in [Appendix D.2](#).

## AIR FORCE

Air Force Instruction 40-402, *Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research*, and Air Force Policy Directive 40-4, *Clinical Investigation and Human Use in Medical Research*, govern human subjects research conducted or supported by the Air Force. As directed by policy, the Air Force Surgeon General must "establish and properly resource the AF [Air Force] HRPP, including [Air Force Medical Support Agency Research Oversight and Compliance Office], to ensure protection and welfare of human subjects in research supported or conducted by the AF."<sup>62</sup> Under the authority of the Air Force Surgeon General, the Air Force Medical Support Agency Research Oversight and Compliance Office oversees implementation and operation of the AF HRPP.<sup>62</sup>

The Air Force Medical Support Agency Research Oversight and Compliance Office also provides support and expertise to the AF HRPP, coordinates policy and interprets regulations, and issues guidance and procedures.<sup>62</sup> The Air Force Medical Support Agency Research Oversight and Compliance Office and its designated human research protection officials provide the reviews necessary to ensure all federal, DoD, and local requirements are met.<sup>41</sup> As described in [Appendix B.2](#), Air Force MTF commanders and Air Force Laboratory Directors are responsible for implementing Clinical Investigation and Human Use Programs in human-use laboratories, Clinical Investigation Facilities, and MTFs.<sup>62</sup> IRBs at Clinical Investigation Facilities support Air Force MTFs with research involving human subjects.<sup>41</sup>

The 59th Medical Wing's Clinical Research Division is the Air Force's largest medical research facility and provides clinical investigations and research support for its investigators.<sup>133</sup> For example, the Clinical Research Division assists with protocol development, research design, biostatistical consultation, laboratory analysis, and veterinary care.<sup>133</sup> Further, the Clinical



Research Division supports operational training requirements for Graduate Health Science Education programs and its providers. The 59th Medical Wing also has a Nursing Research Division, “one of three Air Force nursing research cells dedicated to the conduct of research and the promotion of nursing inquiry.”<sup>133</sup> The Nursing Research Division offers research and evidence-based practice support, as well as grant, protocol, presentation, and manuscript support.<sup>133</sup>

## NATIONAL CAPITAL REGION MEDICAL DIRECTORATE

As noted in [Appendix B.2](#), the clinical research conducted in the National Capital Region Medical Directorate is supported by the Department of Research Programs, headquartered at the Walter Reed National Military Medical Center. The Department of Research Programs has a number of offices, including:

- Business Cell, which provides assistance for “funding, grant writing, technology transfer, informatics, contract management, and comptroller duties;”<sup>87</sup>
- Research Development, which provides assistance with protocol development, biostatistics, research education services, and scientific review;<sup>88</sup>
- Research Oversight Office, which provides regulatory experts to ensure compliance with Federal, State, DoD, local, institutional policies and regulations, and has an education, training, and outreach section;<sup>89</sup>
- Research Compliance Office, which ensures the protection of human subjects in research, provides education to the research community, and identifies strengths and weaknesses of research practices at the Walter Reed National Military Medical Center;<sup>90</sup> and
- Center for Nursing Science and Clinical Inquiry, which provides support for all aspects of research and presentation, such as design and methodology, data analysis, survey development, and manuscript preparation.<sup>91</sup>

## UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

The Uniformed Services University of Health Sciences (USUHS) has a Human Research Protections Program Office, located within the Office of Regulatory Compliance under the Office of the Vice President of Research.<sup>92</sup> The Human Research Protections Program Office is responsible for implementing the DoD Assurance and is the custodian of the Department of Health and Human Services Federalwide Assurance at USUHS. The Human Research Protections Program Office also provides administrative support to USUHS’s two IRBs: USUHS IRB I and the Infectious Disease Clinical Research Program (IDCRP) IRB; reviews or concurs with submissions related to non-human subjects research determinations and research exemption determinations; and conducts internal and external inspections or audits of human research activities for IRB-approved protocols. Further, the Human Research Protections Program Office implements and provides training and guidance on human subject research regulations and requirements for USUHS faculty, staff, and students.<sup>92</sup>

The IDCRP was established in 2005 through an interagency agreement with USUHS and the National Institute of Allergy and Infectious Diseases. Its mission is “to conduct infectious disease clinical research of importance to the military through a unique, adaptive, and



collaborative network to inform health policy and clinical practice and disseminate findings throughout the scientific community.”<sup>67</sup> In terms of research infrastructure, the IDCRP has:

- a Data Coordination Center, which provides expertise and support to principal investigators for the “conceptualization, design, collection, management, analysis and publication of research study data.”<sup>67</sup>
- Regulatory Affairs, which consists of staff located in the IDCRP network’s MTFs and Program Coordination Center, assisting with protocol development, IRB submissions, on-site quality assurance and auditing, tracking publications and presentations, and maintaining regulatory documents.<sup>67</sup>
- Clinical Operations, which is a team of clinical research managers that provides central oversight for multi-site projects. The team coordinates and communicates with principal investigators, Data Coordination Center, and site managers responsible for studies at MTFs.<sup>67</sup>

The IDCRP IRB is a unique DoD IRB; it “creates a single review pathway for multi-center ID [infectious disease] research and eliminates the need for multiple and repetitive scientific, ethical and second level reviews at multiple medical treatment facilities.”<sup>67</sup>

#### ADDITIONAL DEPARTMENT OF DEFENSE REQUIREMENTS TO THE COMMON RULE

As required by 10 U.S. Code Section 980:

Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless- (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.<sup>76</sup>

This prohibition may be waived if the research project advances development of a medical product necessary to the Armed Forces given that it provides direct benefit to the subject and is conducted in accordance with applicable laws.<sup>76</sup> DoDI 3216.02 defines “research involving a human being as an experimental subject,”<sup>77</sup> as “an activity for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction.”<sup>77</sup> DoDI 3216.02 also states, “research involving a human being as an experimental subject is a subset of research involving human subjects.”<sup>77</sup> Therefore, the definition of an experimental subject is narrower than the definition of a human subject.

If a protocol meets the definition of an experimental subject and includes persons who are not able to consent for themselves, then protocols must include a description of how the research is intended to benefit each subject in the protocol for both placebo and treatment arms. If a protocol is determined to be greater than minimal risk, DoDI 3216.02 also requires the IRB approve an independent research monitor with “expertise consonant with the nature of risk(s) identified within the research protocol, whose role is to protect the safety and well-being of human subjects.”<sup>77</sup> Finally, rules and regulations exist that govern studies based on whether the



experimental subject/human subject is a Service member or a member of the public and whether research involves protected health information or MHS data.

## C.2 ADDITIONAL REQUIREMENTS FOR DEFENSE HEALTH PROGRAM MEDICAL RESEARCH

Apart from human subjects research protections, there are other research requirements that DoD investigators may be required to comply with, depending on the type of research conducted. For example, an investigator may have to submit their protocol to an IACUC,<sup>93</sup> institutional biosafety committee,<sup>94</sup> a privacy board,<sup>95</sup> or the protocol investigators may have to undergo a conflict of interest review.<sup>77</sup>

Similar to human subjects research, various laws, regulations, and guidelines set the minimum requirements to be met in order to conduct research involving animals, such as:

- U.S. Department of Agriculture Animal Welfare Act<sup>228</sup> and Animal Welfare Regulations;<sup>229</sup>
- *Public Health Service Policy on Humane Care and Use of Laboratory Animals*;<sup>230</sup>
- *American Veterinary Medical Association Guidelines for the Euthanasia of Animals*;<sup>231</sup>
- *National Research Council Guide for Care and Use of Laboratory Animals*;<sup>232</sup> and
- *Guide for the Care and Use of Agricultural Animals in Research and Teaching*.<sup>233</sup>

DoD has further regulatory guidance for the use of animals in research delineated in DoDI 3216.01<sup>234</sup> and Joint Regulation<sup>\*\*\*</sup> *The Care and Use of Laboratory Animals in DOD Programs*.<sup>93</sup> To ensure DoD animal care and use standards are met for intramural research, DoD requires the submission of a number of forms: a DoD animal use protocol format to an IACUC describing the proposed animal use;<sup>93</sup> Defense Department Form 2856, “DoD Semiannual Program Review/Facility Inspection Checklist” to assist the IACUC;<sup>235</sup> site visit checklists; and reviewer checklists for protocol submissions. Also, per DoDI 3216.01, all DoD’s intramural animal care and use programs are required to be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International.<sup>234</sup>

The DHB was informed that DoD IACUCs have varying degrees of efficiency and proficiency because of insufficient staffing, as well as challenges associated with varying levels of expertise, continuity of expertise, and leadership involvement.<sup>236</sup>

## C.3 INSTITUTIONAL REVIEW BOARD OPERATIONS AND TECHNOLOGY

As described in [Appendix C.1](#), all DoD-conducted or -supported research involving human subjects is governed by DoDI 3216.02, and each of the Services has its own policy related to protection of human subjects in research.<sup>62,78-81</sup> These policies provide direction on the operation of IRBs. Both DoD and non-DoD investigators alike are faced with IRB challenges, which has been cited throughout literature. For example, investigators have noted expanding obligations of

\*\*\* Army Regulation 40–33, Secretary of the Navy Instruction 3900.38C, Air Force Manual 40–401(I), Defense Advanced Projects Research Agency Instruction 18, USUHS Instruction 3203.



IRBs beyond the protection of research participants,<sup>96</sup> excessive study paperwork, strict regulatory requirements, study delays,<sup>97</sup> and increased expenses associated with the IRB process,<sup>98-104</sup> all of which may compromise the ability of researchers to complete studies. It is important to note, however, that some of the challenges experienced by DoD investigators may not be generalizable across DoD IRBs; issues may vary between IRBs.

Although DoD is “examining and streamlining its regulatory practices, reducing duplicative reviews, and unifying requirements” through DoDI 3216.02, currently there is no standardization of IRB forms and processes.<sup>72,73</sup> Currently, each Service and federal agency has different requirements and different methods for implementation of the federal laws governing human subjects research. Further, each Service and the institutions within that Service interpret the implementation of the laws differently.<sup>73</sup>

Recently, the Army agreed to utilize a single protocol template for all Army MTFs; however, the Navy, Air Force, and DHA continue to use forms that contain similar information in different formats, making it challenging to coordinate multi-site studies across the Services.<sup>72</sup> Freed et al emphasized that “standardization would allow for more efficient coordination of multisite studies, reduce confusion and reporting mistakes, and allow investigators and IRBs to focus on scientific and ethical considerations of research.”<sup>72</sup> The MHS’s new electronic IRB system (eIRB), launched in April 2016, will have standardized templates “with smart forms and embedded logic to guide research teams through the entire submission process.”<sup>105</sup> The DHB was made aware that efforts are underway to standardize forms and processes through the eIRB; however, as of October 2016, not all DoD institutions were online with the eIRB system.<sup>106</sup>

Additionally, although DoDI 3216.02 states that “DoD Component policies and procedures shall include a requirement to justify the duplication of reviews of protocols (for example, IRB and Component Headquarters reviews),”<sup>77</sup> the DHB was informed that for multi-site or multi-center studies, multiple IRB reviews were still occurring. Additionally, principal investigators may not be aware that reliance on a single DoD IRB is possible, or there may not be a support system in place to help a principal investigator rely on a single IRB. However, there are a number of DoD institutions that can and do defer IRB reviews through institutional agreements for IRB review. In addition, DoDI 3216.02 currently allows reliance on non-DoD IRBs when DoD’s role is secondary;<sup>77</sup> with the recent revision to the Common Rule that strongly encourages use of a single IRB,<sup>237</sup> DoD will need to determine how to respond to that requirement.

With a few exceptions (e.g., the IDCRP IRB), the DoD IRB system as a whole is decentralized.<sup>41</sup> Moving to a single IRB system would eliminate duplicative ethics reviews, but would not eliminate the necessary reviews and requirements for a performance site’s human research protection program, such as departmental reviews to determine whether there is adequate support for the performance site to conduct the study; institutional education, training, and credentialing requirements; or other committee reviews, such as radiation safety committee reviews, conflict of interest management, other business agreements, or post-compliance monitoring.<sup>78,79,81</sup> However, the use of a single IRB for multi-site research is now a mandate for National Institutes of Health (NIH) funded studies.<sup>107</sup>



The DHB also heard from IRB staff and DoD investigators that delays may be encountered related to the design of the protocol. For example, the protocol may not be feasible in terms of scope or study population, or the investigator may be inexperienced and lack mentorship or support required to develop a high-quality protocol. Therefore, IRB approvals are often delayed while non-IRB issues are resolved. Additionally, DoD IRBs may not have sufficient IRB staff, and they may be overwhelmed with increased workloads.

The previous DoD IRB system, IRBNet, collected metrics evaluating processes (e.g., average time from submission to initial review), as will the new DoD eIRB. However, with the loss of the IRBNet at the end of September 2015, there is a lapse in data until all DoD IRBs are brought online to the new eIRB. The DHB requested IRB metrics from DoD Components to demonstrate IRB process metrics across the Components (Army, Air Force, Navy, NCR MD, and DHA); however, the data were estimates and were limited in providing a robust comparison of IRB process metrics across the Components.

Such process metrics may be helpful predictors of IRB effectiveness<sup>108</sup> and may “better inform funders and researchers about what to reasonably expect from the review process at different military sites and better allow regulators to evaluate existing staffing needs and administrative processes.”<sup>72</sup> Another IRB metric that may be beneficial is the reason for study closure (e.g., loss of funding, science no longer relevant, low accrual). An IRB might have quick review times, minimal administrative burdens, and other costs; however, although these IRB process metrics are informative, they do not directly measure the effectiveness of an IRB in protecting the welfare of human subjects.<sup>108</sup>

Despite challenges faced by DoD investigators and its IRBs, there has been positive movement forward to improve IRB operations. For example, the DHB was notified in August 2016 that the Army Surgeon General approved the consolidation of Army medical center IRBs into regional IRBs; Army will reduce from 10 to 5 medical IRBs.<sup>109</sup> Additionally, the implementation of the new eIRB should help drive standardization of templates and allow agreements to accept other Service’s IRB review through the implementation of the eIRB.<sup>110</sup>

#### C.4 COLLABORATIVE RESEARCH

The key element of collaborative research is “the cooperative relationship between two or more researchers.”<sup>41</sup> There are several variations of collaborative research; for example, collaborative research may involve investigators from two different departments of the same institution or a research project involving federal government and an academic institution or private company.<sup>111</sup> An investigator may choose to collaborate in order to answer research questions; share responsibility; offer assistance navigating department culture or policies or provide expertise; pool financial or human resources; increase funding opportunities; or gain greater credibility. In addition, the enormous wealth of data available in DoD systems provides an extraordinary opportunity for collaborative medical research.<sup>41</sup>

Despite these benefits, there are challenges associated with collaborative research. As noted in the [Appendix C.1](#), each of the Services has its own policy related to the protection of human subjects in research,<sup>62,78-81</sup> which may delay a multi-site/multi-center research project. For multi-



site/multi-center research conducted by DoD, IRBs often agree to rely on one IRB through Institutional Agreements for IRB Reviews.<sup>41</sup> However, investigators at each site are responsible for obtaining local command approval, as required per site.<sup>41</sup> Further, between agencies such as DoD and the Department of Veterans Affairs (VA), a minimum of two IRB reviews is required, as DoD and the VA cannot engage in Institutional Agreements for IRB Reviews given differing review regulations.<sup>41</sup> Agencies such as DoD or the VA may require data sharing agreements to facilitate collaborative research.<sup>41</sup> For DoD, the Defense Health Agency (DHA) requires a Data Sharing Agreement Application before a data sharing agreement is approved for an investigator to use any electronic health record data (e.g., Armed Forces Health Longitudinal Technology Application data). IRB approval is required before these applications are approved, which may further delay research projects.<sup>112</sup>

There also may be credentialing and training requirements, which may delay initiation of a project, or the rotation of staff, (e.g., active duty Service members), which may threaten the continuity of collaborative research. Further, changes in leadership, such as the commander of an MTF, may lead to shifting priorities and possibly a reduction in available resources for projects. Finally, DoD MTF investigators typically do not have protected research time.<sup>41</sup> DoD has implemented various initiatives to improve collaborative research, whether intramural or extramural. For example, the DoD Hearing Center of Excellence has established a Collaborative Auditory and Vestibular Research Network, which “brings together researchers with auditory research foci as a forum to discuss current research across the DoD and VA enterprises, providing unique opportunities for collaboration.”<sup>238</sup> The Hearing Center of Excellence Collaborative Auditory and Vestibular Research Network includes:

- strategically aligned research laboratories;
- military treatment facilities;
- nonprofit and foundation counterparts;
- industry and academic partners;
- international organizations; and
- other government Centers of Excellence.<sup>238</sup>

Another challenging aspect of DoD collaborative research is the process for executing CRADAs and interagency agreements, which will be further discussed in [Appendix C.5](#). CRADAs, which are agreements between a federal laboratory and one or more non-federal partners to conduct collaborative research and development, may be lengthy to process.<sup>239</sup> Further, the CRADA templates are not standardized across the Services; each of the Services uses its own CRADA template.<sup>41,112</sup> The varying CRADA templates as well as the lengthy timelines for processing may discourage collaboration with the DoD. Interagency agreements are requests or acceptance for goods or services between DoD Components or between a DoD Component and non-DoD federal agency,<sup>240</sup> and among its challenges are the different regulations governing different agencies.<sup>113</sup>



## VISIBILITY OF PROJECTS FOR COLLABORATIVE MEDICAL RESEARCH

Having accessible information on planned and ongoing research efforts helps coordinate and accelerate collaborative research.<sup>114</sup> A February 2012 Government Accountability Office report found that “information on health research funded by NIH, DOD, and VA is in different databases with varying types and amounts of information.”<sup>115</sup> The Government Accountability Office recommended that the NIH, DoD, and the VA “determine ways to improve access to comprehensive electronic information on funded health research shared among agency officials and improve the ability of agency officials to identify possible duplication.”<sup>115</sup> Later that year, the Assistant Secretary of Defense for Health Affairs, Congressionally Directed Medical Research Programs, NIH, and VA convened to determine how to use the NIH Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER) for a pilot program. During this time, the NIH developed and tested Federal RePORTER, based on the NIH RePORTER module.<sup>†††</sup>

At the time of the publication of the 2013 National Research Action Plan, the VA was already using the NIH RePORTER.<sup>114</sup> Concurrently, DoD had some medical research portfolio information accessible by public websites; however, the National Research Action Plan stated:

A new commitment will be to analyze the costs, benefits, and utility of moving the DoD’s medical research onto the NIH Research Portfolio Online Reporting Tools system as well as related systems such as Electronic Research Administration Commons, thus promoting a higher level of transparency and analysis across agencies and for the public.<sup>114</sup>

Between 2013 and 2014, the Assistant Secretary of Defense for Health Affairs requested the Congressionally Directed Medical Research Programs administer a pilot project enabling visibility of DHP RDT&E-funded medical research through the Federal RePORTER, and the Joint Program Committee Chairs were directed to plan for improved data sharing using the NIH’s Federal RePORTER and Electronic Research Administration Commons.<sup>116</sup> The pilot project, scheduled to end by Fiscal Year (FY) 2016, has encountered various challenges related to the data transfers and is hoped to be completed in early 2017. Despite these challenges, the Congressionally Directed Medical Research Programs has continued to transfer data to Federal RePORTER using alternative methods; Federal RePORTER currently has over 4,800 project records from the Congressionally Directed Medical Research Programs.<sup>117</sup> To improve collaborative research efforts, DoD and the NIH have also created the Federal Interagency Traumatic Brain Injury Research system, which is an “informatics system . . . developed to share data across the entire [traumatic brain injury] research field and to facilitate collaboration between laboratories, as well as interconnectivity with other informatics platforms.”<sup>243</sup>

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<sup>†††</sup>The NIH RePORTER allows users to search NIH-funded research projects, as well as access publications and patents resulting from NIH funding and is a module on the NIH RePORT website.<sup>241</sup> The NIH RePORT website provides access to reports, data, and analyses of NIH research activities, including information on its expenditures and results of NIH supported research.<sup>242</sup>



There is also the Grants.gov website, which provides a single website for organizations to search and apply for federal discretionary grants. Grants.gov is funded by the 26 grant-making agencies that utilize the website, commensurate with size and usage. In FY 2015, the Department of Health and Human Services and DoD had the highest volume of submissions processed, with 156,073 and 14,218 submissions, respectively.<sup>244</sup> Grants.gov is also used for USAMRMC's Broad Agency Announcements for extramural medical research. Additionally, with the new eIRB system, each Component's headquarters office staff (e.g., Services, Defense Health Agency, USUHS) will be able to see research submissions within their Component; however, there is no direct cross-Component oversight or visibility within the eIRB.<sup>110</sup>

## C.5 TECHNOLOGY TRANSFER

Technology transfer is the process of sharing, transmitting, or conveying technology data and information (intellectual property) between government agencies, industry, and academia.<sup>118</sup> The process usually includes: identifying new technologies, protecting technologies through patents and copyrights, forming commercialization strategies such as marketing, and licensing to private sector companies.<sup>245</sup> The general criteria required for a successful technology transfer program in the government include having an effective Office of Research and Technology Applications (ORTA), engaged researchers, well-managed intellectual property, effective transfer mechanisms, efficient processes, and meaningful communication with industry.<sup>119</sup> The sharing between private sector and the government in regard to technology transfer is a bidirectional relationship and includes more than technology or innovations alone—it also encompasses the sharing of personnel, facilities, methods, expertise, and technical information.<sup>246</sup>

Historically, there have been various forms of legislation enabling and promoting technology transfer within the federal government.<sup>247-250</sup> Most recently, in October 2011, President Barack Obama issued a memorandum that required federal laboratories to improve their technology transfer activities by: 1) developing metrics for successful commercialization activities; 2) streamlining federal technology transfer processes; and 3) facilitating commercialization through local and regional partnerships.<sup>119,251</sup>

## TECHNOLOGY TRANSFER IN THE DEPARTMENT OF DEFENSE

There are multiple technology transfer mechanisms available, including [CRADAs](#), [licensing agreements](#), [material transfer agreements](#), and [interagency agreements](#).<sup>120,121</sup> Technology transfer mechanisms, such as CRADAs, enable the collaborative leveraging of federal and non-federal resources to more efficiently develop products and expertise.<sup>128</sup> DoD is the top agency establishing CRADAs, accounting for 52 percent of all active federal CRADAs in FY 2003.<sup>122</sup> DoD is also a significant contributor to patented technologies and has been enabled by technology transfer opportunities to be one of the world's largest innovators.<sup>122</sup> Department-specific legislation with emphasis on technology transfer, such as the National Defense Authorization Act of 1991 and the National Defense Authorization Act of 1993, have encouraged and required effective transfer policies to be enacted.<sup>246</sup>



Per DoD Instruction 5535.8 and DoD Directive 5535.3:

It is DoD policy. . . that . . . [technology transfer] activities shall be an integral element of the DoD national security mission, a high-priority role in all DoD acquisition programs, and recognized as a key activity of the DoD laboratories and/or technical activities and all other DoD activities that may make use of or contribute to [technology transfer].<sup>126,252</sup>

Although currently the Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics establishes policies for research and development across DoD, technology transfer activities are not managed centrally; instead they are managed by each Service and each laboratory's ORTA.<sup>122,169</sup> For example, it was stated to the DHB that the entire Department of the Navy has approximately 35 laboratories with distinct ORTAs. The ORTA's responsibilities include marketing the laboratory expertise and capabilities; conducting outreach and communications on newly patented technologies; developing technology transfer agreements; and coordinating, as well as conducting laboratory tours. Much of the activity in the ORTAs is focused around the establishment of CRADAs, given the high demand and the value they reap DoD, as well as the industry.<sup>122</sup>

Each of the Services have had successful technology transfer initiatives, such as the Army Research Laboratory's Open Campus initiative,<sup>123</sup> the Navy's Innovation Discovery Process and Military to Market program,<sup>119</sup> and the Air Force Research Laboratory's Information Directorate.<sup>124</sup> However, there is a lack of harmonized and consolidated technology transfer policies, procedures, and templates across the Services. The lack of standardization slows and may discourage inter-Service medical research collaboration. Further, because of differences in technology transfer policies, multi-Service medical research collaborations with non-federal entities (e.g., academia or private sector companies) are largely non-existent. Additionally, the Services' technology transfer programs may vary greatly in their expertise of medical technology transfer and in the depth and experience of ORTA and legal staff, particularly intellectual property support.<sup>128</sup> The Services each provide their own patent support, which operate differently, and the DHA does not have its own patent support; currently, DHA intellectual property needs are supported by the Naval Medical Research Center.

DoD Instruction 5535.8 also states that the Directors of Defense Agencies (e.g., the DHA) are responsible for accomplishing technology transfer in their organization and that all DoD laboratories and/or technical activities capable of supporting or making use of technology transfer make it a high priority.<sup>126</sup> Therefore, a critical component for the effective management of medical research within the DHA is the adoption of standardized technology transfer approaches. On July 1, 2014, the Director of the Defense Laboratory Office, under the Office of the Assistant Secretary of Defense for Research and Engineering, sent a memorandum to the DHA Research and Development Director stating that with the establishment of the DHA, one of the actions the Agency needs to undertake is the development of a common set of technology transfer policies, procedures, and practices.<sup>127</sup> The memorandum continues, "A harmonization of policies, procedures, and practices in [technology transfer] for DHA . . . will enhance DHA's ability to execute its medical research, development, and acquisition mission." In response to this memorandum, a DHA technology transfer program procedural instruction has been drafted and is being routed through the DHA publication process.<sup>128</sup>



## THE PARTNERSHIP INTERMEDIARY APPROACH

Partnership Intermediary Agreements, introduced through the National Defense Authorization Act of FY 1991, stipulate that federal laboratories can enter into agreements with third party intermediaries to facilitate technology transfer activities into the private sector. The primary objective of these entities is to establish CRADAs and patent license agreements for the manufacture and use of DoD technologies.<sup>125</sup>

These organizations are beneficial to the technology transfer process in that they function as a neutral facilitator between the labs and industry. In DoD, agency-wide intermediaries are fully federally funded and do not charge companies for their services—allowing them to not be financially motivated.<sup>122</sup> With the goal of fostering partnerships for technology transfer, they assist DoD in meeting its defense mission and Congressional mandate. They coordinate communication between the two parties, act as mediators, implement best practices in technology transfer processes, and develop effective and complete agreements.<sup>122</sup> Many of the tasks the intermediaries complete are those that the ORTA is not able to accomplish due to their large scope of responsibilities and insufficient capacity. Furthermore, these entities conduct market research to understand the value of DoD's technologies, as well as understand the needs of the marketplace—better matching companies to the types of technologies most appropriate to their interests. They provide services to the private sector, in assisting in the development of high quality CRADA Statements of Work and licensing applications.<sup>122</sup>

## BENEFITS OF TECHNOLOGY TRANSFER

The benefits of technology transfer are vast and include positive scientific and economic impacts. Transferring of technologies developed within DoD strengthens the U.S. industrial base, creates acceptance for commercial off-the-shelf products for government use at reduced costs, creates technology that has applications to both industry and military, and informs academic discussions and applications.<sup>129</sup> Commercialization of DoD's innovations lowers unit costs, drives innovation, and ensures product support.<sup>121</sup> Furthermore, under licensed agreements DoD laboratories benefit from the fees and royalties, which are used to reward the inventors, promote innovation, and support the laboratory's technology transfer programs.<sup>122</sup> Within the context of medical research and development, resource-leveraging collaborations and access to external technologies, training, and expertise are by far the largest benefits. For example, patients get access to novel therapeutics in clinical trials, health care providers can access new technologies and skill sets, and scientists can access critical reagents and expertise.<sup>128</sup>

In 2016, an analysis demonstrated that technology transfer provided an economy-wide impact of \$48.8 billion in output from DoD license agreements, as well as the creation of 182,985 jobs with an average salary of \$71,000.<sup>130</sup> Examining biomedical advancements and sales, the analysis found there to be a wide range of innovations in both preventative and therapeutic advancements, such as vaccines and medicines, diagnostic tests, medical devices, wound care products, antibodies used in research, and health-related software.



## C.6 RESEARCH SUPPORT

There are multiple non-principal investigator members within a research team who are essential for the initiation and conduct of research activities. These include clinical research coordinators, protocol development staff, administrative staff, biostatisticians, medical writers, or budget personnel. Clinical research coordinators, for example, assist with the organization, coordination, and overall integrity of research involving human subjects, providing assistance with activities such as protocol development; subject recruitment; scheduling tests and procedures; collecting research data; and managing the use of investigational devices, among others.<sup>253</sup> As another example, research administrators provide management support and ensure that the funding organization's (e.g., DoD) regulations are followed.<sup>254</sup>

Many of these support staff are available for DoD investigators through the previously described programs, such as the Department of Research Programs at the Walter Reed National Military Medical Center. However, the availability of these essential research support staff varies between DoD institutions, especially at MTFs. Other important issues to consider include recruitment, education and training, career development, and continuity of research support staff. Civilian and contract staff must conduct research activities only as outlined in their position description and the project's statement of work.<sup>41</sup> Additionally, contract staff funded with science and technology dollars performing research within MTFs or research laboratories may not provide clinical care unless privileged by the facility or under the clinical privileges of an assigned provider.<sup>41</sup>

DoD research institutions often need to rely on outside, temporary funding to hire essential research support personnel, such as through the Henry M. Jackson Foundation or contracts. However, bringing on research staff through contracts may take weeks to months, depending on the contract mechanism used and degree of infrastructure available. Additionally, contract support staff may not receive benefits such as health care, vacation, or sick leave.<sup>41</sup> Therefore, there may be higher turnover of contract staff and less support available for DoD research activities.

In FY 2012, DoD began an initiative that uses DHP RDT&E program element 6.6 funding to support research infrastructure and sustain technical subject matter expertise at DoD research sites and MTFs. The goals of the initiative include:

- accelerating delivery of trauma therapies and regenerative medicine therapies for severely injured Service members;
- expanding combat casualty care, psychological health, and rehabilitative medicine knowledge base;
- developing models of injury; and
- testing advanced technology products.<sup>131</sup>

This initiative helps DoD investigators to compete more effectively for DHP RDT&E funding and conduct medical research by providing research support personnel (Table 3). Further, this initiative provides relevant DoD patient populations the opportunity to participate in clinical research and clinical trials, thereby improving patient outcomes.



**Table 3.** Research Support Personnel Supported by DHP RDT&E Program Element 6.6 Funding

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

From Defense Health Agency, 2016.

According to the Defense Health Agency Research and Development Directorate, more than \$23 million in DHP RDT&E program element 6.6 funds have been provided since FY 2012 to help maintain or expand clinical research capabilities and research support personnel at numerous research sites and MTFs across DoD (Table 4).<sup>131</sup> However, the DHB has been informed that although certain MTFs have taken advantage of this program, such as the Naval Medical Center San Diego, there has been hesitancy to participate by other MTFs. One factor limiting the development of research infrastructure may be reluctance to request RDT&E funds due to the unfounded fear that use of these funds for this purpose is non-allowable.

**Table 4.** Recipients of DHP RDT&E Program Element 6.6 Funding FY 2012 to FY 2016

Army	Brooke Army Medical Center Eisenhower Army Medical Center Landstuhl Regional Medical Center Madigan Army Medical Center Tripler Army Medical Center Womack Army Medical Center
Navy	Naval Hospital Camp Pendleton Naval Hospital Pensacola Naval Medical Center Portsmouth Naval Medical Center San Diego
Air Force	Wilford Hall Ambulatory Surgical Center David Grant Medical Center
Office of the Assistant Secretary of Defense for Health Affairs	Uniformed Services University of the Health Sciences Uniformed Services University of the Health Sciences – Infectious Disease Clinical Research Program
Defense Health Agency – National Capital Region Medical Directorate	Walter Reed National Military Medical Center National Intrepid Center of Excellence

From Defense Health Agency, 2016.



Other important elements of research infrastructure are the facilities in which research is conducted, such as medical laboratories or vivariums. In a 2011 Center for Strategic and International Studies report on overseas medical laboratories, the authors highlighted the lack of sufficient, predictable, and sustainable core funding, stating:

This chronic deficiency in core funding motivates laboratories to take on research and program opportunities beyond their primary missions. . . Although these ancillary activities bring in significant funding and benefit global health and the U.S. military, they require infrastructure, personnel, and time-dependent research to satisfy contracts, threatening to crowd out the laboratories' primary missions.<sup>14</sup>

This is also echoed in a 2015 Government Accountability Office report on DoD's chemical and biological defense facilities, such as the U.S. Army Medical Research Institute of Infectious Diseases.<sup>37</sup> This report highlights funding challenges, noting that the facilities receive funding through individual research and development projects awarded by the Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense through the Joint Science and Technology Office. U.S. Army Medical Research Institute of Infectious Diseases officials also informed the Government Accountability Office "that it would be helpful if the [Chemical and Biological Defense Program] Enterprise provided stable, sustainment funding in a way similar to the funding received for the test and evaluation facilities."<sup>37</sup>



## APPENDIX D. PROFESSIONAL DEVELOPMENT OF DEPARTMENT OF DEFENSE INVESTIGATORS

The Department of Defense (DoD) offers numerous opportunities for both military and civilian personnel to conduct medical research. For example, DoD conducts research related to undersea and aerospace medicine,<sup>210,211</sup> vaccines for infectious disease such as dengue and malaria,<sup>7</sup> and combat casualty care.<sup>8</sup> However, a number of factors have led to the loss of experienced medical research talent over the last decade,<sup>138,139,255</sup> including those military and civilian personnel with clinical and scientific expertise. This attrition is related to a number of issues, including:

- fiscal pressures,
- increasing administrative burdens,
- repeated deployments in support of combat operations,
- lack of clarity on research career tracks, and
- the perception that medical research is not valued in tangible ways, such as enhancing ones' prospects for promotion.

Thus, young investigators are left with fewer experienced mentors and a perception that there are limited opportunities for advancement in a research career path. As described in the Defense Health Board's (DHB's) 2015 report, *Continuing Education for Department of Defense Health Professionals*, DoD policies have restricted the ability of investigators to attend professional conferences, leading to:

- a limited presence of DoD investigators in these important meetings;
- reduced visibility and sharing of Defense Health Program (DHP) medical research; and
- reduced opportunities to network and create research partnerships.<sup>136</sup>

### D.1 RECRUITMENT, DEVELOPMENT, AND RETENTION OF DEPARTMENT OF DEFENSE INVESTIGATORS

To become a military health professional, a qualified individual is either directly commissioned into a Service; accessed through the Uniformed Services University for the Health Sciences (USUHS); or accessed through the Health Professionals Scholarship Program.<sup>137</sup> If active duty military personnel wish to conduct medical research, they may become involved through a number of different pathways. The most common opportunities for research are through DoD research laboratories and military treatment facility (MTF) Clinical Investigation Programs (CIPs).<sup>41</sup> Military personnel with the appropriate education and training can conduct research at dedicated research facilities, such as the Walter Reed Army Institute of Research, the Naval Medical Research Center, or the Air Force Research Laboratory. Further, personnel may pursue academic affiliation with a civilian or military institution; a position as a faculty member at a Service academy or other military institution (e.g., USUHS); a position as a student, intern, or fellow in a military education program (e.g., San Antonio Uniformed Services Health Education Consortium); or a position as a student or faculty member in a civilian academic institution (e.g., R. Adams Cowley Shock Trauma Center at the University of Maryland).<sup>41,256</sup>

Civilian DoD personnel may conduct research as a clinician at an MTF or may be hired as a scientist by a DHP medical research laboratory.<sup>41</sup> Similar to military personnel, civilian personnel may hold faculty positions at military or civilian institutions or conduct research as a



trainee in a military education program. However, the funding sources for civilian personnel vary by Service and include federal and contract positions.<sup>41</sup> DoD civilian investigators may be recruited through programs such as the Oak Ridge Institute for Science and Education program, which helps DoD laboratories obtain post-doctoral fellows, as well as retain technical subject matter expertise through the Knowledge Preservation Program, which allows retirees to consult for an organization.<sup>147</sup> There are also Education Partnership Agreements, which allow DoD laboratories to partner with degree-granting institutions and engage graduate students at those institutions.<sup>147</sup>

## CHALLENGES FOR RETAINING ACTIVE DUTY INVESTIGATORS

Between 2007 and 2009, multiple assessments were conducted of the recruitment and retention of military health professionals.<sup>138,139,255</sup> These reviews identified significant shortages in physicians, nurses, dentists, and other medical officers.<sup>138,139,255</sup> A few of the reasons cited for challenges in recruitment and retention were limited supply of and high demand for qualified health professionals; lower pay than the private sector; stresses, length, and frequency of deployment; and length of commitment required to stay in the service.<sup>139</sup> To improve recruitment, the Services may offer accession bonuses or special pay for medical officers in certain specialties.<sup>140</sup> However, the DHB was informed that special pay for research activities is limited; currently, only the Navy offers a Dental Officer Multi-Year Retention Bonus to dental researchers.<sup>150</sup> In contrast, special pays for research are available for commissioned officers in the U.S. Public Health Service.

Each Service has a number of research-oriented career paths under the Medical Service Corps or Biomedical Science Corps, such as microbiology, research physiology, or behavioral health. However, for the Services' (Army, Navy, and Air Force) Nurse Corps, Medical Corps, and Dental Corps, few published descriptions of medical research career paths were identified.<sup>141-143</sup> The Army Medical Department lists research as one of three assignment tracks (clinical/operations, education, and research) in its Officer Development and Career Management pamphlet, but there is little written guidance on how an officer may pursue that assignment track.<sup>142</sup> Army has an Additional Skill Identifier and Navy has an Additional Qualification Designation code that their officers may apply for that is related to research; Air Force does not have a Special Experience Identifier for research.<sup>†††</sup> Although these codes may help demonstrate additional qualifications of a military officer for his or her promotion boards, similar to how an additional certification may be considered as a distinguishing factor, they are not as influential to one's promotion as being part of designated career track.

A 2011 Center for Strategic and International Studies report notes the challenge of conducting medical research in DoD with the frequent rotation of active duty personnel, which "constrains the institutional memory necessary to long-term research projects; impedes mentorship of

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<sup>†††</sup>Army has Additional Skill Identifier 8Z for medical research, development, test, and evaluation. Navy has Additional Qualification Designation 6ZF for "Researcher," requiring that the officer a) completed an IRB approved research project fully consistent with the guidelines as promulgated by the Naval Health Sciences Education and Training Command; and b) met the rigorous guidelines of their medical community for publication in a peer-reviewed journal.



younger scientists; and hinders the career progression of scientists who rarely see their research through to completion.”<sup>14</sup> The authors recommended a dedicated medical research career track to provide improved incentives for research, help recruit talented researchers, and cultivate valuable scientific expertise.<sup>14</sup> In a 2016 journal article by Pruitt et al, the authors discuss the successes of DHP medical research, particularly combat casualty care research at the U.S. Army Institute of Surgical Research, noting that:

The current policy of limiting the assignment of the commander to a period of only 2 years can only be considered an undesirable limitation since a 2-year assignment will not allow a commander to develop and oversee completion of a research project, let alone a research program.<sup>8</sup>

The authors continue that brief command assignments make it challenging to develop a leadership vision and emphasize that the commander of the U.S. Army Institute of Surgical Research should be a surgeon or “clinically experienced, research-capable medical scientist.”<sup>8</sup> Additionally, research activities may not be weighted heavily in a military officer’s evaluation for promotion. The 2011 Center for Strategic and International Studies report authors note that “although medical research differs greatly from other military deployments, performance is evaluated on the same criteria. As a result, a tour at an overseas laboratory can lower an officer’s chance of promotion.”<sup>14</sup> Throughout the DHB’s roundtable discussions with DHP medical research policy leaders, as well as military investigators at all levels of experience, it was clear that medical research was not perceived as significantly valued in an officer’s evaluation for promotion, particularly for those conducting clinical research at MTFs.

As evidenced by the Fiscal Year 2017 National Defense Authorization Act, there is an evolutionary change occurring in how the Military Health System (MHS) is approaching health care administration, including the movement toward value-based health care, adoption of core quality performance metrics, and accountability of certain leaders for the performance of the MHS.<sup>23</sup> Currently, the MHS uses relative value units to measure outpatient production targets.<sup>1</sup> These targets are set using benchmarks established by the Medical Group Management Association and do not include research. DoD targets using these benchmarks are Service- and specialty-specific; the MHS goal is for at least 75 percent of providers to meet productivity targets by Fiscal Year 2018.<sup>145</sup> In the Fiscal Year 2016 Defense Health Program Budget Estimate Volume 1, it is stated, “for [Fiscal Year] 2014, the system produced 78 million relative value units versus a goal of 81 million relative value units. The MHS failed to achieve the goal for the year, but expects continued improvements in the coming years.”<sup>1</sup> Therefore, commanders at MTFs are under pressure to meet or exceed relative value unit standards. The DHB was told that patient care contributes to generating relative value units; however, medical research activities do not. Further, research is not viewed as a critical mission of the MTFs. Through roundtable discussions, the DHB also frequently heard that, at MTFs, investigators lacked dedicated research time. Thus, clinicians motivated to conduct research or those who need to complete scholarly activity requirements for Graduate Medical Education (GME) typically have to do so on their own time.



DHP medical research, development, test, and evaluation laboratories and MTFs quantify investigators' research productivity by tracking the following:

- peer-reviewed publications (e.g., full length manuscripts);
- other publications, such as abstracts, posters, editorials, or case reports;
- presentations at national or international conferences;
- new cooperative research and development agreements;
- patents filed; and
- active, completed, or new protocols.<sup>146,147</sup>

These metrics are useful for tracking the scholarship of MTF CIPs, as well as the scholarship of other DHP medical research institutions. However, throughout roundtable discussions with DoD investigators, it was revealed that these metrics do not explicitly contribute to the performance evaluation of MTF commanders; therefore, MTF commanders may not be incentivized to promote research at MTFs, apart from achieving the minimum scholarly activity threshold as required by the Accreditation Council for Graduate Medical Education (ACGME).

### CHALLENGES FOR RETAINING DEPARTMENT OF DEFENSE CIVILIAN INVESTIGATORS

There are also challenges associated with retaining civilian DHP medical researchers. Currently, federal agencies such as the Departments of Defense, Health and Human Services, Justice, and Veterans Affairs have delegation agreements under 38 U.S. Code sections 7431-7433 (Title 38) with the U.S. Office of Personnel Management for employees providing “direct patient-care services or services incident to direct patient-care services.”<sup>148,149</sup> These agreements establish higher rates of basic pay for “an occupation or group of occupations nationwide or in a local area based on a finding that the Government’s recruitment or retention efforts are, or would likely become, significantly handicapped without those higher rates.”<sup>149(p.6)</sup> DoD Instruction 1400.25, Volume 543 establishes policy, assigns responsibilities, and provides procedural guidance for setting the pay of DoD civilian physicians and dentists consistent with various federal statutes, including Title 38.<sup>257</sup> Per this policy, “Physicians and dentists will be compensated at levels that are reasonably comparable with the total pay of physicians and dentists employed in similar positions in other Federal healthcare facilities and in the private and non-Federal sectors.”<sup>257</sup> This Instruction outlines the implementation of the Physicians and Dentists Pay Plan, which follows the pay table and tier structure established by the Department of Veterans Affairs. However, Title 38 may only be used to hire and compensate civilian physicians and dentists in the competitive service; Title 38 is not applicable to other health care professionals unless they are hired in the excepted service.<sup>150</sup>

The Department of Health and Human Services and the Environmental Protection Agency also have unique hiring authority under 42 U.S. Code §§ 209, sections (f) and (g), (Title 42) to fill mission critical scientific and medical appointments. Title 42 enables these agencies to compensate its employees above the salary limits applicable to federal employees.<sup>151</sup> DoD does not have Title 42 hiring authority to recruit and retain high-quality scientists.<sup>150</sup> As a result, DoD is less competitive in hiring and retaining civilian researchers compared to other federal agencies or in the biotechnology and pharmaceutical industries for the improved monetary incentives.



Further, the 2011 Center for Strategic and International Studies report states that U.S. Army and Navy medical research laboratories “remain under-resourced, both in funding and in personnel; and their achievements are poorly appreciated at the policy levels within Congress and the Executive Branch.”<sup>14</sup> These laboratories must compete for funding through grants; proposals to DoD sponsors; and cooperative research agreements with other federal agencies, academia, or industry.<sup>14</sup> Therefore, as a result of uncertainty of the budget year-to-year, DoD medical laboratories may not have the funding necessary to hire or retain sufficient research personnel. Throughout roundtable discussions with DoD investigators at medical research, development, test, and evaluation laboratories, it was stated to the DHB that often, laboratories rely on contractors to fill personnel gaps; however, contractors may also depart for better paying, more stable research positions elsewhere.

While most of the DHB’s discussions were focused on the physician investigator, the DHB was also unable to ascertain a clear career pathway for a doctoral-level investigator in DoD. Of note, it appeared to the Board that the majority of physician scientists were recruited to the military to provide care and subsequently moved to research; no such opportunities appeared to exist for doctoral-level non-clinicians. However, the U.S. Army Medical Research Institute of Infectious Diseases is in the early stages of implementing a Tenure Track Program.<sup>258</sup> This program will be a centrally managed process to identify and assess scientific capability gaps that can be met by a government scientist, and then recruits, hires, mentors and evaluates those individuals through progression from term to permanent employees.<sup>258</sup>

## D.2 EDUCATION AND TRAINING

Scholarly activity is a Common Program Requirement for accreditation by the ACGME for all specialties. The 2015 ACGME Common Program Requirements state that faculty “must establish and maintain an environment of inquiry and scholarship with an active research component” and “should encourage and support residents in scholarly activities.”<sup>152</sup> For resident scholarly activities, it is mandated that educational program curricula “must advance residents’ knowledge of the basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care.”<sup>152</sup> Additionally, the “sponsoring institution and program should allocate adequate educational resources to facilitate resident involvement in scholarly activities.”<sup>152</sup>

ACGME has Residency Review Committees for each specialty that “propose requirements for revising residency program accreditation standards and ensuring compliance with individual programs’ standards,”<sup>153</sup> such as a specialty’s scholarly activity requirements. However, there currently is no uniform definition of scholarly activity used by all Residency Review Committees.<sup>154</sup> Further, there is no standardized methodology for assessing resident and faculty scholarly activity. In a 2012 study aimed at defining scholarly activity, the authors found that only 6 of the 27 Residency Review Committees had a rubric or draft of a rubric to evaluate scholarly activity.<sup>154</sup>

As previously stated in Appendix B.2, the CIPs “support Graduate Health Sciences Education and other allied health programs of the Military Services” and “promote high professional standing and accreditation of health education and training programs within the MHS.”<sup>18</sup>



Therefore, the CIPs support completion of scholarly activity requirements. However, with no uniform definition for scholarly activity nor significant formal education and training provided by medical schools, residencies, or fellowships on developing meaningful research questions, clinical investigators in DoD are at a disadvantage. Further, the trainees have limited time to complete the research, may lack knowledge on how to find funding, and must meet relative value unit requirements; additionally, their mentors may have limited experience themselves.<sup>155,156</sup>

Lack of proper education and training for the conduct of high-quality research can lead to poorly developed protocols, which then clog Institutional Review Boards (IRBs). Rather than addressing the ethical and regulatory requirements of a protocol, the IRB must address shortfalls in the protocol design. Additionally, the research project may be left unfinished, which has implications for the ethics of the research.<sup>157</sup> Each Service's GME program may also receive citations from the ACGME for not meeting scholarly activity requirements.<sup>158</sup>

There are a limited number of initiatives available to help build a cadre of military investigators within DoD. These include:

- the Army Medical Department's two-year [Clinical Research Fellowship at the San Antonio Uniformed Services Health Education Consortium](#);<sup>259</sup>
- the [Tri-Service Nursing Research Program](#) based out of USUHS;<sup>214</sup>
- the [Master of Public Health, Master of Tropical Medicine and Hygiene, and Master of Science in Public Health programs](#) at USUHS;<sup>260</sup>
- the Naval Medical Center San Diego's 10 credit [Research Methods Training Program](#);<sup>132</sup> and
- four to six-week health surveillance and epidemiology rotations of preventive medicine and occupational and environmental residents as well as Master of Public Health/Master of Science of Public Health students from the Walter Reed Army Institute of Research and USUHS, hosted by the [Armed Forces Health Surveillance Branch Epidemiology and Analysis Division](#).<sup>261</sup>

The Services also frequently have workshops or seminars that help meet some of the training requirements for the investigators. For example, the Army CIP hosts a semiannual Clinical Investigation Research Training Seminar at Joint Base San Antonio with other 150 local attendees, and the Services' human research protection programs provide the minimum education requirements for DoD personnel involved in human subjects research,<sup>§§§</sup> such as Collaborative Institutional Training Initiative training.

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<sup>§§§</sup>Minimum education requirements for DoD personnel involved in human subjects research are determined by the Assistant Secretary of Defense for Research and Engineering and the Office of the Under Secretary of Defense for Personnel and Readiness.



### D.3 MENTORING

Mentoring can be defined as “a dynamic, reciprocal relationship in a work environment between an advanced career incumbent (mentor) and a beginner (protégé) aimed at promoting the career development of both.”<sup>159</sup> Mentoring may be divided into two categories: research mentoring and career mentoring.<sup>160-163</sup> Research mentoring involves developing the research career of the mentee through skills acquisition, selecting and conducting research projects, presenting research findings at professional meetings, writing and submitting manuscripts, protocol development, grant applications, and learning how to obtain funding. In contrast, career mentoring may focus on career promotion, balancing professional and personal obligations, or major career decisions.<sup>164</sup> Mentoring may also be formal or informal; formal mentoring involves a more committed relationship to ensure the protégé has a successful research career.<sup>164</sup> Jackson et al discussed that, for mentoring relationships to be successful, the mentor and protégé must be compatible, and the protégé may need to experiment with various mentors to find the right match.<sup>262</sup>

In 2006, Sambunjak et al conducted a systematic review of 42 articles regarding “the evidence about the prevalence of mentorship and its relationship to career development.”<sup>263</sup> In this review, mentorship was reported to be an important influence on personal development, career guidance and choice, and research productivity, such as publication and grant success.<sup>263</sup> Benson et al also indicated that mentoring programs positively influence junior and senior faculty satisfaction and improve productivity and retention, even during times of reorganization and minimal availability of resources.<sup>264</sup> Further, mentoring can improve preparation of protégés to serve as mentors and increase perceptions of a supportive academic environment.<sup>264</sup> Benson et al suggested that mentorship should be available throughout training and career establishment, but the mentorship qualities required at these different stages may differ.

In 2011, a working group was formed to establish a leadership development program for Army physicians. The working group noted “few Medical Corps officers are interested in pursuing leadership positions outside of the clinical arena,” and “Medical Corps officers who attain clinical or command leadership positions are often unfamiliar with the principles of leadership practice and theory.”<sup>165</sup> The working group recognized the existence of informal mentoring relationships for Army physicians, but reported that there were insufficient time and resources to facilitate mentoring relationships, there was no centralized structure to identify mentors, and most Army Medical Corps officers serving as mentors had not received formal training related to mentoring. Additionally, there was a lack of executive coaching opportunities, and these few opportunities were not centrally funded.<sup>165</sup> This working group did not specifically address mentoring of medical researchers; however, it did recommend creating a matrix cross-linking Army Medical Corps career paths (e.g., clinical, academic, research) with required education and recommended experience in order to help the Army identify physician leaders to serve as future commanders and senior leaders. A recent commentary by Sood et al highlights that “a mentor training program is one component of a supportive mentoring environment but is unlikely to be well subscribed to unless the institutional culture encourages participation.”<sup>265</sup> Therefore, while mentoring is valuable for the mentor, protégé, and the institution, the institution must first encourage the existence of formal mentoring relationships.



These findings have also been reinforced throughout the DHB’s roundtable discussions with DoD investigators, who noted the importance of mentorship to help navigate the complex administrative processes for initiating and conducting medical research in DoD, as described in [Appendix B](#). However, investigators frequently cited the lack of senior investigators available to provide such mentorship for junior investigators.

In 2010, the DHB conducted a review of the DoD Center for Deployment Health Research at the Naval Health Research Center, finding “a dearth of senior level uniformed military medical professionals who have the depth of knowledge of the disease and injury experience of military personnel” and “few senior investigators on the staff.”<sup>266</sup> The DHB recognized the challenges associated with availability of senior investigators, such as advancement in rank and frequency in rotation, but suggested the issue “should be pursued with the goal of having a broader distribution of investigators at all stages of seniority.”<sup>266</sup> Although there is a shortage of DoD senior investigators, it is important for DoD to invest in mentorship to develop its cadre of junior investigators, reduce attrition of talented personnel, and create a future network of experienced research mentors to advance medical research. It is also important for the research mentor to be engaged in ongoing programs to maintain relevant skills in both research and mentoring and to be recognized and rewarded for their mentoring efforts.

#### D.4 INDIVIDUAL ATTENDANCE AND PARTICIPATION AT RESEARCH CONFERENCES/FORUMS

A 2014 report published by the National Academy of Sciences noted that professional conferences and meetings bring together large concentrations of junior and senior researchers, allow for informal information exchange, and provide access to the newest research findings. The authors state, “maintaining knowledge through literature is inadequate as there can be a one to two year lag between peer-review publication and current discovery.”<sup>166</sup> They also note the importance of attendance at professional conferences and meetings for early career investigators, which provide them the opportunity to network and build relationships. Further, not engaging in such venues may harm the reputation of laboratories and their ability to recruit top investigators.<sup>166</sup>

Individual participation in professional meetings and conferences by DoD’s medical researchers helps to improve the visibility of DoD’s contributions to medical research, including the breadth and depth of its medical research endeavors. DoD sponsors an annual meeting, the Military Health System Research Symposium, which allows DoD investigators, academia, and industry to exchange information on research and health care advancements in military-relevant areas, such as Combat Casualty Care.<sup>167</sup> The Military Health System Research Symposium provides an opportunity to recognize successful DoD investigators, assess MHS research priorities, and build collaborative relationships. It also provides an opportunity for DoD laboratory directors and directors of CIPs to regularly communicate on new or existing processes, policies, or regulations that hinder medical research and to facilitate early recognition of problems and their resolution.

In 2011, high profile misspending at conferences sponsored by the Department of Veterans Affairs and the General Services Administration led to the publication of policies by the Office of Management and Budget, the President, and the Deputy Secretary of Defense restricting



conference attendance and participation. Because of these policies and subsequent updates, conference review and approval processes became lengthier, and conference attendance decreased.<sup>134</sup> A 2015 Government Accountability Office report identified that risks associated with changes in conference participation included “a potential decline in the quality of scientific research, difficulty in recruiting and retaining qualified scientists and engineers, and a diminished leadership role for DOD and [Department of Energy] within the global [science and technology] community.”<sup>134</sup>

The 2015 DHB report, *Continuing Education for Department of Defense Health Professionals*, reviewed in depth the challenges associated with attending professional conferences as a military health professional. The Board provided numerous recommendations to the Department related to attendance at such conferences, including streamlining approval processes for military health professionals to participate in conferences; ensuring opportunities for regular in-person participation; and prioritizing funding for individuals serving as a presenter, moderator, or military liaison at an approved conference or meeting. The Board also recommended simplifying approval processes for non-federal source travel and expediting approval, within ethics and conflict of interest guidelines, for invited DoD presenters and contributors utilizing non-federal source travel.<sup>136</sup>

In 2013, the DoD Deputy Chief Management Officer established three tiers for reviewing and approving conference-spending requests; the total cost of the conference and whether it was DoD-sponsored or non-DoD-sponsored determined the review and approval tier.<sup>267</sup> DoD published new guidance on conference attendance on September 23, 2015, which includes delegation of approval authority to the lowest appropriate level and encourages pre-approval of recurring conferences.<sup>268</sup> Although conference attendance restrictions have been loosened, the DHB was informed that they continue to hinder attendance of DoD investigators. Recognizing the importance of conference attendance, the 21st Century Cures Act of 2016 notes that “it is the sense of Congress that participation in or sponsorship of scientific conferences and meetings is essential to the mission of the National Institutes of Health,”<sup>269</sup> thereby providing “much-needed relief from restrictions on support for scientific meetings.”<sup>168</sup> However, such loosening of travel restrictions for conferences appears to only be afforded to investigators from the Department of Health and Human Services.<sup>168</sup>

Continued restrictions on attendance of DoD investigators at professional meetings and conferences are harmful to the individual investigator, as well as the military medical research enterprise. Not participating in such venues restricts the opportunity to disseminate military medical research findings and priorities, build sustaining relationships, advertise the unique opportunities to conduct research at MTFs and DoD medical laboratories, and recruit talented medical researchers.



## APPENDIX E. ATTRIBUTION OF DEFENSE HEALTH PROGRAM MEDICAL RESEARCH SUCCESSES

A 2015 article on combat casualty care research states, “Research is taken from the bench to the bedside or vice versa and repeated until the gap is filled, as we strive to move current care toward best care.”<sup>270</sup> In an editorial on U.S. military tropical medicine, the authors state that the “US military has consistently worked to develop new disease control tools, including drugs, diagnostics, and vaccines,” which “significantly affect our warfighters and protectors while simultaneously aiding and empowering the world’s poor who are also plagued by these debilitating diseases.”<sup>6</sup> Therefore, as highlighted throughout this report, military medical research plays a vital role in advancing patient care and population health for both civilian and military populations. However, another necessary aspect for the advancement of medicine is the dissemination of research innovations. There are a number of mechanisms to disseminate research findings, such as internal and external marketing, professional publications, and professional conferences and meetings, each of which will be further discussed below. The Defense Health Program (DHP) research, development, test, and evaluation (RDT&E) portfolio supports intramural and extramural medical research;<sup>41</sup> a majority of the portfolio is extramural. Therefore, it is important that both extramural and intramural research funded by the Department of Defense (DoD) is acknowledged and recognized through enhanced visibility of the contributions of DHP research.

### E.1 INTERNAL AND EXTERNAL MARKETING

As previously described in [Appendix C.5](#), technology transfer is the process of sharing, transmitting, or conveying technology data and information between government agencies, industry, and academia.<sup>245</sup> The processes involved may include identifying new technologies, protecting technologies through patents and copyrights, forming commercialization strategies (e.g., marketing), and licensing to companies.<sup>245</sup> Transferring DoD-developed technologies helps create acceptance of off-the-shelf products, creates technology that has applications to both industry and the military, and informs academic discussions and applications.<sup>129</sup> Additionally, commercializing DoD’s innovations may help lower unit costs, drive innovation, and ensure product support.<sup>121</sup>

Each of the Services has its own Office of Research and Technology Applications; additionally, most of the medical RDT&E laboratories have an Office of Research and Technology Applications.<sup>122,169</sup> These offices develop technology transfer agreements, usually through cooperative research and development agreements; market the laboratory’s expertise and capabilities; and conduct outreach and communications on newly patented technologies.<sup>122</sup> There are also Partnership Intermediary Agreements, which allow federal laboratories to enter into agreements with third party intermediaries to facilitate technology transfer activities into the private sector.<sup>114</sup> These third party intermediaries establish cooperative research and development agreements and patent license agreements for the manufacture and use of DoD technologies, completing many of the tasks that Offices of Research and Technology Applications do not have the resources to support. For example, the third party intermediaries conduct market research to understand the value of DoD’s technologies and the needs of the marketplace.<sup>114</sup> As such, DoD Offices of Research and Technology Applications, Partnership



Intermediary Agreements, and the research-related agreements they coordinate are important components of the marketing of DoD-developed or funded research.

## STRATEGIC COMMUNICATION OF DEFENSE HEALTH PROGRAM MEDICAL RESEARCH

DoD provides access to unique resources for research, such as the DoD Serum Repository – a biorepository of serum and tissue samples that have been collected by the Department since 1989 and has been leveraged for the recent Cancer Moonshot initiative.<sup>170</sup> There is also the Millennium Cohort Study, based out of the Naval Health Research Center, which is the largest prospective health study in the military with more than 200,000 participants and provides the opportunity to study the various effects of deployment on the health of Service members.<sup>171</sup> There are also the unique capabilities provided by the Services’ medical laboratories, such as high altitude research chambers<sup>172</sup> or operational and undersea medicine.<sup>173</sup> Communicating such unique capabilities and their value to the overall medical research enterprise, whether DoD or civilian, is critical to the continued success of DHP medical research programs.

The breadth of strategic communications of medical research capabilities and accomplishments is varied across the numerous DoD research execution agents that receive DHP funding. For example, the U.S. Army Medical Research and Materiel Command publishes yearly “Command Accomplishments” reports, as well as product portfolios, strategic information papers on subordinate commands (e.g., Walter Reed Army Institute of Research), and U.S. Army Medical Research and Materiel Command articles and press releases.<sup>174</sup> The Navy publishes fact sheets highlighting the capabilities and accomplishments of its medical research and development laboratories,<sup>175</sup> as well as monthly newsletters,<sup>176</sup> and it highlights recent news articles online.<sup>177</sup> The Air Force also lists recent medical research news articles and maintains fact sheets on the Air Force Research Laboratory<sup>179</sup> and the 59th Clinical Research Division that are accessible online.<sup>180</sup>

At the institution and program level, many of the Army subordinate laboratories also showcase recent peer-reviewed articles by their civilian and active duty investigators on their websites, as do some of the Joint Program Committee-managed core research programs. For example, the Combat Casualty Care Research Program advertises its research portfolio, recent peer-reviewed articles, and has a “monthly scientist highlight” on its website. However, for the Clinical Investigation Programs, neither the regional military treatment facility that houses the Army’s Department of Clinical Investigation, the Navy’s Clinical Investigation Department, nor the Air Force’s Clinical Investigation Facility have a website providing the mission and vision of the program. Currently, none publicly advertises recent peer-reviewed articles.

However, a Military Health System Studies Inventory Tool was recently developed and implemented that “allows easy review of recent studies that are either conducted or sponsored by the Military Health System, or accomplished using datasets developed or maintained by the Defense Health Agency for administrative, operational, or research purposes.”<sup>181</sup> The tool currently has 213 abstracts listed, published between 2012 and 2016, and efforts are underway to populate additional publications from across the MHS into the tool. However, this tool primarily includes studies that cover the realm of health services research. This tool provides an



opportunity to advertise and provide further visibility on the health services research conducted by DoD investigators.

The Congressionally Directed Medical Research Programs publishes an annual report that provides background on the program and its research portfolio, which includes a few pages highlighting some of the DHP RDT&E research activities under the various Joint Program Committees for which it provides execution management support.<sup>11</sup> However, there is no separate annual report of equivalent detail and length for DHP medical research, including both DHP RDT&E and Clinical Investigation Programs, which could be used to help market the various successes and capabilities of research supported by the DHP appropriation. For the Clinical Investigation Programs, there is the previously mentioned annual report provided to the Assistant Secretary of Defense for Health Affairs, but it is not a formal report nor is it released for public distribution. Thus, there appears to be no unified strategic communications plan for DHP medical research. As noted by Bonk et al:

A communications plan is an important part of an organization's daily operation. As a living document, it frames media activities, including internal and external communications, clarifies the organization's priorities, target audiences, resources and staff assignments.<sup>271</sup>

Therefore, a unified strategic communications plan for DHP-funded medical research (both RDT&E and Clinical Investigation Programs) would help clarify DoD's medical research priorities, its target audiences, and its available resources.

## E.2 PUBLICATION OF DEFENSE HEALTH PROGRAM MEDICAL RESEARCH IN PEER-REVIEWED JOURNALS

[Appendix E.1](#) describes the important components of internal and external marketing of DHP medical research. Another component of attribution of DHP medical research innovations is the dissemination of such findings in peer-reviewed journals. It has been stated that "the dissemination of valuable and novel scientific information provides the pulse for biomedical publishing," and "scientific journals catalog the contributions, thoughts, and opinions of researchers, investigators, and experts in the field."<sup>272</sup>

There are a number of policies that must be followed before the public release and dissemination of DHP medical research.<sup>41</sup> For example, the investigator must consult their relevant Institutional Review Board and Public Affairs Office before publication. Further, research must be vetted by Operational Security to ensure no confidential or strategic intelligence is publicly released, and the research may need reviews by higher level Public Affairs Offices (e.g., U.S. Navy Bureau of Medicine and Surgery). The Army, Navy, and Air Force all have differing procedures for clearance of research for publication, and these procedures may vary between facilities.<sup>41</sup>

As noted in [Appendix E.1](#), many of the medical laboratories and some of the Joint Program Committees provide lists of recent peer-reviewed articles on their websites; some lists of articles are more up-to-date than others. The visibility of such peer-reviewed articles helps highlight the



innovative medical research and productivity of DoD investigators. There are also bibliometric <sup>\*\*\*\*</sup> services available to DoD investigators, such as the Walter Reed Army Institute of Research Gorgas Memorial Library, which also supports the Naval Medical Research Center, and uses Journal Citation Reports<sup>®</sup> to help identify the most “appropriate, influential journals in which to publish.”<sup>274</sup> The Gorgas Memorial Library may also assess “the research performance of a program area by examining its publications and viewing the journal article impact and strength of research influence using citation metrics.”<sup>274</sup> For example, in 2011 Walter Reed Army Institute of Research conducted a bibliometric evaluation of “[Excellence in USAMRU-Kenya \[U.S. Army Medical Research Unit-Kenya\] Research](#).”<sup>274</sup>

Similar services are available at the Darnall Medical Library at the Walter Reed National Military Medical Center, which provides support services for literature reviews, manuscript development and publication, and data management.<sup>275</sup> The Washington University of St. Louis’s Barnard Becker Medical Library has another model that libraries may use to assess the impact of medical research, similar to Walter Reed Army Institute of Research’s, assessing: dissemination of research, use of research output and activities, translation of research into clinical applications, changes to policy and legislation, economic outcomes, and enhancement of community health.<sup>276</sup> Such frameworks for research performance evaluations may:

- help quantify and document research impact;
- provide data-driven justifications for future requests for funding;
- quantify return on research investment;
- map how research findings are being used; and
- identify similar research projects and possible collaborators.<sup>274,276</sup>

In addition to the standard medical literature, there are peer-reviewed journals that are venues for military-specific research or federal medicine, such as the *Medical Surveillance Monthly Report*, *Military Medicine*, and *Federal Practitioner*. DoD investigators can consult with their available bibliometric services to identify the most appropriate peer-reviewed journals in which to publish their findings.

### E.3 PRESENCE AT NON-DEFENSE HEALTH PROGRAM MEDICAL RESEARCH CONFERENCES AND FORUMS

[Appendix D.4](#) describes the importance of individual attendance of DoD investigators at professional conferences and the current limitations. There are numerous benefits associated with attendance at professional conferences and meetings, including subspecialty conferences. The previously cited 2014 National Academy of Sciences report on DoD’s strategic engagement in global science and technology strongly emphasized the importance of participation in such venues, citing them as necessary for:

- providing a venue for scientists and engineers to present their work, as opposed to journal papers;

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<sup>\*\*\*\*</sup> Bibliometrics is “the application of quantitative analysis and statistics to publications such as journal articles and their accompanying citation counts.”<sup>273</sup>



- allowing researchers to network and build research collaborations;
- maintaining global science and technology awareness through a diversity of inputs; and
- preventing DoD in-house research from becoming “insular and noncompetitive.”<sup>166</sup>

The authors added, “DoD should have an in-person presence at international [science and technology] fora to establish for itself a reputation as a leading contributor to the international research community.”<sup>166</sup> Also, “in-person interactions are critical for building sustained, trusted research collaborations and for better understanding each country’s or region’s unique [science and technology] strengths and gaps.”<sup>166</sup>

Recently, U.S. Army Medical Research and Materiel Command headquarters and laboratory personnel from a few of its subordinate laboratories participated in the June 2016 BIO International Convention, bringing together over 15,000 leaders in the biotechnology and pharmaceutical fields. This convention allowed the Army to exhibit its medical research capabilities, help form potential collaborative partnerships, and advance the mission of the Army. Additionally, as a result of participation in the convention, “negotiations are underway to take technologies from discovery in the lab to effective end user products.”<sup>277</sup> Thus, presence at non-DoD sponsored conferences is critical for demonstrating DoD’s unique medical research capabilities, its successes, and the value it reaps the military and civilian communities, as well as building and strengthening collaborative research partnerships.



APPENDIX F. REQUEST TO THE DEFENSE HEALTH BOARD



UNDER SECRETARY OF DEFENSE  
4000 DEFENSE PENTAGON  
WASHINGTON, DC 20301-4000

SEP 30 2015

MEMORANDUM FOR PRESIDENT, DEFENSE HEALTH BOARD

SUBJECT: Request for Defense Health Board Review of “Improving Defense Health Program Medical Research Processes”

I request that the Defense Health Board (DHB), pursuant to the attached Terms of Reference (TOR) on “Improving Defense Health Program (DHP) Medical Research Processes,” provide recommendations to the Department regarding approaches that would optimally support military medical professionals who oversee and conduct DHP medical research. The DHB, through the Public Health Subcommittee, should examine the processes for conducting DHP medical research and Clinical Investigation Programs within the Department of Defense (DoD) and provide recommendations to improve the visibility of ongoing DHP medical research across the enterprise, improve the efficiency of initiating and conducting high quality research without compromising safety or data protection standards, and encourage more professionals to become engaged in medical research. Specifically, I request 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.
- 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.

The TOR for this review provides a detailed description and scope of the tasking. The point of contact for this action is Ms. Christine Bader. She can be reached at (703) 681-6653, or christine.e.bader.civ@mail.mil. Thank you for your continued support and commitment to optimizing the health and force-readiness of the military.

  
Brad Carson  
Acting

Attachment:  
As stated



## APPENDIX G. TERMS OF REFERENCE

These Terms of Reference establish the objectives for an independent review of processes for initiation, funding, oversight and conduct of Defense Health program medical research in the Department of Defense (DoD).

**Mission Statement:** The mission of the Defense Health Board (DHB) is to provide independent advice and recommendations to maximize the safety and quality, as well as access to, health care for members of the Armed Forces and other DoD health care beneficiaries, including with respect to health research programs.

**Issue Statement:** The Defense Health Program (DHP) appropriation funds medical research and Clinical Investigation Programs (CIP) that are essential missions of the Military Health System (MHS). The purpose of these programs is to optimize the health and performance of the total force, improve the quality of patient care, develop medical products unique to the needs of warfighters, and maintain a medical research portfolio responsive to the needs of the MHS. The goal is to conduct research in support of the MHS Quadruple Aim of readiness, better care, better health, and lower cost. Research may be conducted at laboratories (CONUS and OCONUS), medical treatment facilities, or academic centers. DHP research is comprised of research, development, test, and evaluation (RDT&E) funds and managed through the Defense Medical Research and Development Program. CIPs are supported by DHP operation and maintenance (O&M) funds. Within this funding structure, which restricts use of O&M funds for RDT&E work and vice versa, investigators and oversight functions may have little visibility on research conducted outside of their funding source or institution. In addition, the Institutional Review Board (IRB) structure within DoD is decentralized, and investigators who wish to conduct multicenter clinical trials or studies must obtain separate IRB approval from each participating location.

**Objectives and Scope:** The Public Health Subcommittee (hereafter “Subcommittee”) will address the following specific objectives related to DHP medical research.

- Determine how DoD may improve visibility on 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, and attaining approval, 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.
- Determine how DoD may improve IRB 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.



The Subcommittee shall develop findings and recommendations on the above topics for consideration by the DHB under the open-meeting provisions of the Federal Advisory Committee Act. The DHB, in consultation with the Under Secretary of Defense for Personnel and Readiness or designated representative, may consider other matters deemed pertinent to improving the funding, visibility, oversight, efficiency and effectiveness of conducting relevant DHP medical research.

**Methodology:**

1. The DHB and Subcommittee assessment will be conducted in compliance with the Federal Advisory Committee Act, DoD Instruction 5105.04, and the DHB Charter.
2. The Subcommittee's assessment should focus on identifying barriers to visibility on DHP medical research being conducted across the MHS, inefficiencies in the processes related to initiating multicenter collaborative medical research, and other obstacles that may deter more professionals from becoming engaged in medical research of value to the DoD. In developing findings and recommendations for consideration by the DHB, the Subcommittee will review existing policies, programs and procedures; however, its work will not involve advice on the actual conduct of specific ongoing or potential DoD scientific research projects.
3. The Subcommittee will recommend specific actions to improve the visibility of ongoing DHP medical research across the enterprise, reduce unnecessary administrative obstacles, especially to initiating and conducting multi-center collaborative research, and encourage more professionals to become engaged in high-quality medical research.
4. The Subcommittee may conduct interviews as appropriate.
5. As appropriate, the Subcommittee may seek input from other sources with pertinent knowledge or experience.

The Subcommittee will review processes for tracking, managing, and funding DHP medical research within DoD, administrative processes for initiating and conducting DHP research to include multicenter collaborative studies, and what health professionals perceive as incentives and disincentives for becoming engaged in medical research in DoD. As needed, members will receive briefings from subject matter experts. DoD personnel involved in IRB processes, funding, oversight, and conduct of research, and representatives of academic and clinical programs. The Subcommittee will review the literature and information received from briefings, conduct site visits as needed, and present findings and recommendations to the DHB for consideration and deliberation. The DHB will deliberate the findings and recommendations, during which time members may propose changes, and vote on the final findings and recommendations in a properly noticed and open public session.



## APPENDIX H. MEETINGS AND PRESENTATIONS

### October 29, 2015

On this teleconference, members discussed the tasking and a potential way forward, and they received an overview of Defense Health Program medical research from representatives of the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency.

### December 17, 2015

Bethesda, Maryland

Members received an overview of the Defense Health Program research, development, test, and evaluation program from a Defense Health Agency representative. Members also held roundtable discussions with junior, mid-level, and senior investigators as well as research leadership on Defense Health Program medical research challenges and opportunities for improvement.

In attendance were representatives from the following organizations/institutions:

- Air Force Medical Service;
- Air Force Office of the Surgeon General;
- Defense Health Agency;
- Office of the Assistant Secretary of Defense for Health Affairs;
- U.S. Army Medical Research and Materiel Command;
- U.S. Navy Bureau of Medicine and Surgery;
- Uniformed Services University of the Health Sciences
- Walter Reed Army Institute of Research; and
- Walter Reed National Military Medical Center;

### January 28, 2016

On this teleconference, members held discussions with human subjects research representatives from the Services (Army, Navy, and Air Force) and the Office of the Under Secretary of Defense for Personnel and Readiness.

### March 4, 2016

San Antonio, Texas

Members met with Army, Air Force, and civilian investigators and research administrators to discuss Defense Health Program medical research challenges and opportunities for improvement.

In attendance were representatives from the following organizations/institutions:

- 59th Medical Wing;
- Brooke Army Medical Center/San Antonio Military Medical Center;
- Center for the Intrepid;
- Hearing Center of Excellence;
- San Antonio Uniformed Services Health Education Consortium;



- U.S. Army Institute of Surgical Research; and
- Wilford Hall Ambulatory Surgical Center

### **April 19, 2016**

On this teleconference, members reviewed the draft guiding principles, draft report sections, and discussed future briefings. There were no briefings on this teleconference.

### **May 17, 2016**

Fort Detrick, Maryland

Members met with mid-level and senior active duty and civilian investigators to discuss Defense Health Program medical research challenges and opportunities for improvement.

In attendance were representatives from the following organizations/institutions:

- 59th Medical Wing;
- 711th Human Performance Wing;
- Air Force Medical Support Agency;
- U.S. Navy Bureau of Medicine and Surgery;
- Defense Health Agency;
- U.S. Army Medical Research and Materiel Command;
- Naval Health Research Center;
- Naval Medical Research Center;
- National Institutes of Health;
- Office of the Assistant Secretary of Defense for Health Affairs;
- Office of the Assistant Secretary of Defense for Research and Engineering;
- U.S. Air Force School of Aerospace Medicine;
- U.S. Army Center for Environmental Health Research;
- U.S. Army Medical Research Institute of Chemical Defense;
- U.S. Army Medical Research Institute of Infectious Diseases; and
- Walter Reed Army Institute of Research.

### **June 30, 2016**

On this teleconference, members discussed challenges and opportunities for improvement associated with Defense Health Program collaborative research with subject matter experts from the Madigan Army Medical Center.

### **July 19, 2016**

On this teleconference, members discussed the use of private foundations for Defense Health Program medical research as well as challenges and opportunities for improvement with subject matter experts from the Henry M. Jackson Foundation for the Advancement of Military Medicine.

**August 17, 2016**

On this teleconference, members reviewed the draft findings and recommendations. There were no briefings on this teleconference.

**September 14-15, 2016**

Falls Church, Virginia

At this meeting, members reviewed the draft report sections, findings, and recommendations. Members also met with Military Health System medical research leadership as well as budget personnel to discuss Defense Health Program medical research challenges and opportunities

**October 12, 2016**

On this teleconference, members reviewed the draft report, findings, and recommendations. There were no briefings on this teleconference.

**November 17, 2016**

On this teleconference, members reviewed the draft report. There were no briefings on this teleconference.

**December 15-16, 2016**

Falls Church, Virginia

At this meeting, members reviewed the draft report, findings, and recommendations. Members also met with Uniformed Services University of the Health Sciences representatives to discuss Defense Health Program medical research challenges and opportunities.

**January 18, 2017**

On this teleconference, members reviewed the draft report, findings, and recommendations. There were no briefings on this teleconference.

**February 9, 2017****Defense Health Board Meeting**

Falls Church, Virginia

Dr. H. Clifford Lane, Subcommittee chair, presented the deliberative pre-decisional draft of the report. Defense Health Board members requested additional edits to the findings and recommendations and asked for public comments on the report to be sent to the Defense Health Board support staff.



**March 17, 2017**

On this teleconference, members reviewed comments received on the deliberative pre-decisional draft of the report. There were no briefings on this teleconference.

**April 18-19, 2017**

Falls Church, Virginia

At this meeting, members reviewed the draft report, findings, and recommendations. Members also met with Office of the Assistant Secretary of Defense for Health Affairs, Defense Health Agency, Uniformed Services University of the Health Sciences, Army, and Air Force representatives to discuss DHP medical research challenges and opportunities.

**June 26, 2017**

**Defense Health Board Meeting**

Falls Church, Virginia

Dr. H. Clifford Lane, Subcommittee chair, presented the revised deliberative pre-decisional draft of the report. The Board unanimously approved the findings and recommendations with one revision.



**APPENDIX I. ACRONYMS AND GLOSSARY**

<b>Acronyms</b>	
ACGME	Accreditation Council for Graduate Medical Education
AMC	Army Medical Center
ASBREM COI	Armed Services Biomedical Research and Evaluation Management Community of Interest
ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASD(NCB)	Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs
ASD(R&E)	Assistant Secretary of Defense for Research and Engineering
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CID	Clinical Investigation Department
CIF	Clinical Investigation Facility
CIHUP	Clinical Investigation and Human Use Program
CIP	Clinical Investigation Programs
CRADA	Collaborative research and development agreement
DCI	Department of Clinical Investigation
DHA	Defense Health Agency
DHB	Defense Health Board
DHP	Defense Health Program
DoD	Department of Defense
DoDI	Department of Defense Instruction
eIRB	Electronic Institutional Review Board
FY	Fiscal Year
GAO	Government Accountability Office
GME	Graduate Medical Education
HJF	Henry M. Jackson Foundation for the Advancement of Military Medicine
HRPO	Human Research Protection Office
HRPP	Human Research Protection Program
IACUC	Institutional Animal Care and Use Committee
IDCRP	Infectious Disease Clinical Research Program
IRB	Institutional Review Board
IRBO	Institutional Review Board Office
JPC	Joint Program Committee



MHS	Military Health System
MTF	Military treatment facility
NCR MD	National Capital Region Medical Directorate
NDAA	National Defense Authorization Act
NIH	National Institutes of Health
O&M	Operations and maintenance
ORP	Office of Research Protections
ORTA	Office of Research and Technology Applications
RDT&E	Research, development, test, and evaluation
RePORTER	Research Portfolio Online Reporting Tools Expenditures and Results
RVU	Relative value unit
S&T	Science and technology
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
USD(P&R)	Under Secretary of Defense for Personnel and Readiness
USUHS	Uniformed Services University of the Health Sciences
VA	Department of Veterans Affairs
WRNMMC	Walter Reed National Military Medical Center
<b>Glossary</b>	
Research	Any systematic study directed toward fuller scientific knowledge or understanding of military healthcare and in support of health readiness solutions that protect, treat, and optimize the health and performance of the total force. <sup>18</sup>
Common Rule	The Common Rule is a federal policy regarding Human Subjects Protection that applies to 17 Federal agencies and offices. It does not apply to federal agencies that have not signed the agreement (e.g., Department of Labor, etc.) The main elements of the Common Rule include: <ul style="list-style-type: none"> <li>• Requirements for assuring compliance by research institutions;</li> <li>• Requirements for researchers' obtaining and documenting informed consent; and</li> <li>• Requirements for IRB membership, function, operations, review of research,</li> </ul>



	and record keeping. <sup>74</sup>
Defense Health Program appropriation	A single appropriation consisting of operation and maintenance; research, development, test, and evaluation; and procurement funds designed to finance the non-military personnel requirements of the MHS. <sup>18</sup>
Clinical investigation	An organized inquiry into and possible development of knowledge or products related to clinical health problems for any conditions of concern in providing healthcare to the beneficiaries of the MHS including active duty personnel, dependents, and retired personnel. Clinical investigations represent a special category of healthcare research. Clinical investigations are intended to improve quality of medical, dental, nursing and allied health science care provided to beneficiaries of DoD health services or support the graduate health sciences education programs, other allied health programs of the Military Services, and USUHS. <sup>18</sup>
Cooperative research and development agreements	Broad transfer mechanisms in that any aspect of the RDT&E activity, such as personnel, services, facilities, equipment, intellectual property, or other resources, can be provided by the federal laboratory. <sup>120</sup>
Interagency agreements	Include Service Agreements, Memorandum of Understandings, and Memorandum of Agreements, which allow two or more federal agencies to exchange information, personnel, equipment, material, resources, and funds. <sup>121</sup>
Licensing agreements	Contracts between owner of the intellectual property and the licensee, which permit the licensee to use this intellectual property in accordance with contract terms. <sup>120</sup>
Material transfer agreements	Unidirectional, short-term agreements in which scientists can exchange materials or information. <sup>121</sup>



## APPENDIX J. PUBLIC COMMENTS RECEIVED

Below are comments received on the February 9 pre-decisional draft of the report, including comments from the Board during the February 9 presentation and non-attribitional comments received in the weeks after.

### Comments related to report narrative:

- 1) **General Comment:** The draft DHB uses the term "Defense Health Program research," with a definition of at least 2 separate meanings. One meaning in the DHB report is the appropriation that is provided to Health Affairs/Defense Health Agency to administer, and which totals about \$1.9 million in FY2017. Within the DoD medical research offices, the term "DHP research" usually has this narrow definition.
- 2) **General Comment:** A different meaning in the DHB report for "DHP research" is "all research that is funded by some office within DoD." This very broad meaning includes research funded by HA/DHA, the Army, Navy, Air Force, USU, DARPA, DTRA, CIP, and other offices. This includes intramural and extramural research. Most, but not all, of the possible DoD sources of funding for medical research are shown on Figure 1 on page 2. Note that within the DoD medical research offices, the term "DHP research" is not usually used to mean "all research that is funded by some office within DoD."
- 3) **General Comment:** Some recommendations do not take into account the authorities of ASD(HA) and ASD(R&E).
- 4) **General Comment:** The DHB Report addresses the need for T2 but does not adequately: 1) reflect the importance of T2 in current and future medical research efforts; 2) address the disparity of T2 processes among the DOD services, which DHA was designed to consolidate. Furthermore, Intellectual Property, which is integral in effective management of T2 processes, is not addressed at all.

T2 is vital in conducting and managing effective research programs and moving technology to the warfighter. As the DHB Report indicates, DOD medical research requires intramural and extramural support to accomplish its purposes/mission, be those collaborations in the MTFs (for either medical training or in support of Requirements-based research) or by/in the laboratories on the RDT&E side. Leveraging of DOD with extramural collaborations is vital in addressing many militarily important medical research requirements. T2 collaborations, in the form of collaboration and licensing agreements, is important to fill gaps not able to be filled within existing DOD resources and can significantly accelerate getting medical advances to the warfighter. Those collaborations come about as a result of T2 policies, procedures, and practices. The DHB Report sets forth the current status quo: the military services and the DHA/NCR each manage their own T2 programs, and there are significant differences between these programs.

A significant disadvantage suffered by the DOD medical laboratories over other DOD agencies is the lack of harmonized and consolidated T2 policies, procedures, and templates



within the MHS. The lack of harmony among the services slows and greatly discourages interservice medical research collaborations on both the clinical and requirements-based sides (much like the lack of a common/unified IRB policies and procedures does). Furthermore, the T2 programs of the services vary greatly in their expertise in the specialized nuances of medical T2 and in the depth and experience of ORTA and legal staff, including Intellectual Property support. As such, critical to effective management of research by DHA, is the adoption of, within the DHA medical R&D T2 community “best practices.” Furthermore, the Report does not discuss the need for providing patent support within DHA, whether that is through the services, as it currently exists, or through a consolidated approach.

Recent DOD policy dictates that harmonization of T2 processes should be brought about among the services. Little progress has been made. However, the relevant DOD issuances make it clear that not only the Secretaries of the Military Departments, but also the Directors of the Defense Agencies (read: “Director DHA”), are responsible for establishing and operating their T2 programs. (See, e.g., DODD 5535.3, paragraph 5.2, and DODI 5535.8, paragraph 5.3.) The responsibility for the Director, DHA to undertake to bring about an orderly and effective consolidation of activities, programs, and organizations into a cohesive T2 unit was communicated to the DHA RDA Director in a July 1, 2014 Memorandum from the Director, Defense Laboratory Office (see attached letter).

T2 is part and parcel of an effective medical research infrastructure. Collaborations, which are vital in medical research, cannot occur without an effective T2 process. Furthermore, without T2, because of the high cost of most medical research, new products would either not be developed or be delayed to the warfighter using DOD resources only. Additionally, T2 is a common and basic business function of any medical research organization. The Director, DHA, as discussed above, is required to exercise management responsibility and develop “appropriate management models to most effectively and efficiently assume responsibility” (DODD 5136.13, paragraph 5a(11)).

It should be noted that the T2 practitioners of the three DoD services (i.e., DOD medical T2 trenches) have made a large effort for over three years—beginning soon after the creation of DHA—to bring order to the current situation to the accomplish the above. As a result of their efforts, a DHA Procedural Instruction (PI), SUBJECT: Medical Technology Transfer Program, has been written and is being staffed. The proposed PI (attached) would harmonize MHS T2 policies, procedures, and formats, as it would be applicable to the medical R&D activities funded through the DHP appropriation. The proposed PI also states: “To improve efficiencies, the Services are encouraged to participate in this unified technology transfer process for their respective medical R&D activities within the Military Health System (MHS) utilizing non-DHP funding.”

With the accelerating consolidation of the MTFs under DHA supervision, and the creation of enhanced multi-service markets with rotating (military service) managers in command, it is increasingly important that one set of rules be established for those who are responsible for the T2 programs (ORTAs) and their legal advisors who assist them and help negotiate with



non-federal collaborators, and who together, help provide definition and shape to the needed DOD medical R&D collaborations.

**RECOMMENDATION:** DOD (HA) and the DHA RDA J9 should champion the effort to establish a consolidated and harmonized medical T2 program within the MHS, including through the proposed Procedural Instruction now being staffed.

**RECOMMENDATION:** Insert the following at line 960:

Technology Transfer mechanisms, such as CRADAs, enable the collaborative leveraging of Federal and non-Federal resources to more efficiently develop products and expertise. All Defense Agencies (e.g., DHA) are required to have a technology transfer program under DODD 5535.3 and DODI 5535.8, and the Director, DoD Laboratories Office (OASD(R&E)) informed DHA, RDA (J9) in a memorandum of 1July2014.

**RECOMMENDATION:** Insert the following at line 964:

Given the critical importance of collaboration to medical R&D, technology transfer mechanisms are a fundamental requirement; and this is borne out by the numbers. For example, the entire Department of the Navy has approximately 35 laboratories with distinct ORTAs. While only 3 support Navy Medicine, they account for 40% of the Department's total CRADA transactions.

**RECOMMENDATION:** Insert the following at line 972:

Due to differences in technology transfer policies, multi-service medical research collaborations involving non-Federal entities (e.g., Universities, hospitals, Pharma, etc.), are largely non-existent. However, in response to the OASD(R&E) memorandum charging the DHA to institute a harmonized independent program, a DHA technology transfer instruction was collaboratively drafted and has been ambling through the DHA publications process.

**RECOMMENDATION:** Insert the following at line 981:

However, within the context of medical R&D, resource-leveraging collaborations and access to external technologies, training, and expertise are by far the largest benefits. For example, patients get access to novel therapeutics in clinical trials, health-care providers can access new technologies and skill sets, and scientists can access critical reagents and expertise.



**Comments related to findings and recommendations:**

Objectives, Findings, and Recommendations	Comments
<p><b>1. Determine how the Department of Defense may improve visibility on DHP medical research supported through separate funding sources (RDT&amp;E and O&amp;M) to enhance coordination of effort, oversight, and collaboration.</b></p>	
<p><b>Finding 1:</b> The Department of Defense’s medical research enterprise is fragmented across the Services with an array of different approaches to accomplish common goals. Despite clear direction in Department of Defense Instruction 6000.08 stating that one of the objectives of the Defense Health Program-funded medical research and Clinical Investigation Programs 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. Specifically:</p>	



Objectives, Findings, and Recommendations	Comments
<ul style="list-style-type: none"><li>• The periodic Capabilities Based Assessments are one attempt to try to provide a comprehensive view of ongoing medical research and set priorities. However, it is not clear how follow up takes place in the interim to assure research activities are aligned with these priorities.</li><li>• 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.</li><li>• Although the Defense Health Agency Research and Development Directorate 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, there is no external, independent oversight of both Defense Health Program-funded medical research and Clinical Investigation Programs as a whole. This lack of independent, comprehensive oversight compromises the ability to provide long-term strategic guidance.</li><li>• Defense Health Program-funded medical research 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</li></ul>	



<b>Objectives, Findings, and Recommendations</b>	<b>Comments</b>
Department of Defense medical research funding to support the mission of the Military Health System.	



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 1a:</b> The Director of the Defense Health Agency Research and Development Directorate should have direct oversight over all Defense Health Program research (both research, development, test, and evaluation and Clinical Investigation Programs) in accordance with the spirit of the Fiscal Year 2017 National Defense Authorization Act.</p>	<ul style="list-style-type: none"> <li>• <b>Board Discussion on 2/9/17:</b> Board members suggested including language regarding development of an overall strategy for health research with particular attention to the needs of the warfighter.</li> <li>• Members also suggested replacing “medical research” with “health research” throughout the report, providing a clear definition on what “health research” encompasses from the perspective of the Subcommittee.</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Comments:</b> Discussion regarding the deletion of “Program” to suggest a broader scope. Success will hinge on an authority to oversee these activities. That authority does not exist. It would be based on goodwill; therefore, an authority should be identified.</li> <li>• Consistent with the principles upon which the DHA Research and Development Directorate was founded.</li> <li>• The Director should develop a strategy to identify, coordinate and disseminate DHP funded medical research. Emphasize: This should be the “core” intent of recommendation 1a.</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Comments:</b> Clarity needed on “direct oversight” noted.</li> <li>• <b>Comments:</b> I propose to add the following: “The Director of the Defense Health Agency RDT&amp;E should have direct and regular communication with DoD laboratory directors and Directors of Clinical Investigation Programs to discuss new or existing processes, policies or regulations that hinder biomedical research. This would facilitate early recognition of problems and its resolution.”</li> </ul>



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 1b:</b> The Defense Health Agency Research and Development Directorate should issue a comprehensive biennial report on the status of Department of Defense-conducted medical research taking highlights from the different programs across the Services. This report should be made readily available to the public.</p>	<ul style="list-style-type: none"> <li>• <b><u>Board Discussion on 2/9/17:</u></b> The Board proposed that the Subcommittee recommend key metrics with respect to progress on the strategy outlined in Recommendation 1a.</li> <li>• <b><u>Comments:</u></b> “emphasizing impact” should replace “taking highlights”</li> </ul>
<p><b>Recommendation 1c:</b> The Defense Health Agency Research and Development Directorate should ensure that all Defense Health Program research, development, test, and evaluation-funded medical research is entered into Federal RePORTER.</p>	<ul style="list-style-type: none"> <li>• <b><u>Comments:</u></b> It might be helpful to add the qualifier “non-classified” to the phrase, “...All Defense Health Program research, development...entered into Federal RePORTER.”</li> <li>• <b><u>Comments:</u></b> Strongly support.</li> </ul>
<p><b>Recommendation 1d:</b> The Defense Health Agency Research and Development Directorate should ensure that all clinical trials conducted with Department of Defense funds, both internal and external, are listed on ClinicalTrials.gov.</p>	<ul style="list-style-type: none"> <li>• <b><u>Board Discussion on 2/9/17:</u></b> Members discussed whether this recommendation should also include health research conducted by DoD, regardless of funding source.</li> <li>• <b><u>Comments:</u></b> Strongly support.</li> </ul>



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 1e:</b> The Department of Defense should create a platform, overseen by the Defense Health Agency Research and Development Directorate, which provides visibility of all Department of Defense-conducted medical research, including Defense Health Program-funded medical research and Clinical Investigation Programs, line-funded research, other Department of Defense-funded research (e.g., Defense Threat Reduction Agency and Defense Advanced Research Projects Agency), and extramurally-funded research.</p>	<ul style="list-style-type: none"> <li>• <b>Comments:</b> Support, but this will be a challenge. Must get concurrence of line commands unless authority conferred on DHA R&amp;D directorate. Consider phasing in later to allow infrastructure to be available to provide real time DoD medical research portfolio status. Start with DHP oversight, then add “other monies” research.</li> <li>• This goes hand in hand with recommendation 1a. Need to say it one way or the other.</li> <li>• <b>Comments:</b> Clarity needed on what is meant by the term “platform”</li> </ul>
<p><b>2. Determine the major challenges that Department of Defense investigators face in initiating, funding, conducting, and publishing DHP medical research.</b></p>	
<p><b>Finding 2:</b> Despite the Department of Defense Instruction 6000.08 to maintain a medical research portfolio responsive to the needs of the Military Health System, there is no clear evidence that medical research has been embraced as a clear mission for the Department of Defense. Specifically:</p> <ul style="list-style-type: none"> <li>• There is a lack of a clearly defined career path for officers skilled in medical research, an exodus of current officers with this skill set, and, as a result, a shortage of mentors for junior officers with this interest.</li> <li>• There is no intentional recruitment of officers with medical research training. Individuals are</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Comments:</b> <i>“Lack of a clearly defined career path”</i> The services differ with respect to career paths for officers skilled in clinical research (more below), but there are examples in all 3 Services of stellar officers who have managed to spend most, if not all of their career between deployments in research roles marked by progressive responsibility. This may have more to do with these officers’ determination than mentoring, but the system is not as broken as the committee portrays. I worry that a blanket statement this strong overlooks those who are succeeding and demotivate others who wish to develop such a path. It might be helpful to propose a survey of current and former officers who have been successful to identify what shortfalls/obstacles they see.</li> </ul>



<b>Objectives, Findings, and Recommendations</b>	<b>Comments</b>
recruited because of their clinical skills with little or no thought given to their research qualifications.	



Objectives, Findings, and Recommendations	Comments
<ul style="list-style-type: none"> <li>• Given the primary focus of commanders on clinical care relative value units, there is variable and generally limited command support for Clinical Investigation Programs research with investigators often taking this task on after required duty hours.</li> <li>• While it was often stated that Defense Health Program research, development, test, and evaluation and operations and maintenance funds could not be combined to support Clinical Investigation Programs research, the Board could find no such restriction and, in fact, instruction to the contrary.</li> <li>• 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 non-Department of Defense sources. Accordingly, the research agenda is at risk of being driven by funding opportunities as opposed to the genuine needs of the warfighter.</li> </ul>	<ul style="list-style-type: none"> <li>• <i>“No intentional recruitment of officers with medical research training.”</i> This statement is too sweeping as well. As the leadership academy for military health, the Uniformed Services University of the Health Sciences (USU) considers medical research training a highly desirable attribute in applicants. Likewise, our health professions students (medicine, nursing, dental, clinical psychology, public health, etc.) routinely interact with research mentors skilled at basic, translational, clinical and/or population health science. We also offer upper-level students the option of capstone experiences focused on research. Last year, half the graduating medical students did a capstone. In addition, when clinical department chairs reach out to service specialty consultants to bring active-duty faculty on board for assignments at USU, we specifically target those with academic interests so we can develop them. Finally, we seek uninformed clinical chairs and deans where possible as a pinnacle assignment in their academic careers. Outstanding examples include COL (Ret) Kent Kester, COL (Ret) Mark Kortepeter, COL (Ret) Scott Miller, CAPT (Ret) Mark Stephens, CAPT Tim Burgess, Col Todd Rasmussen, COL Fran O’Connor, COL Shad Deering, CAPT Eric Elster and COL Nelson Michael, among others.</li> </ul>



Objectives, Findings, and Recommendations	Comments
	<ul style="list-style-type: none"> <li>• <i>“Variable and generally limited command support for Clinical Investigation Programs research.”</i> The MHS’ current focus on RVUs is driven by congressional and DoD officials who believe that use of this metric is essential to make the system more clinically “productive.” However, civilian health systems with high rates of RVU production generally rely on fee-for-service billing, have modest or nonexistent population health, research and education programs, and have no requirement to sustain readiness. The readiness mission is vital to the MHS. In my opinion, so is “research readiness” – the capacity to problem solve and rapidly innovate when confronted with new or emerging health threats. The NEJM article ... recently published (attached) comments on this.</li> <li>• <i>“No apparent restriction on mixing DHP RDT&amp;E and O&amp;M funds”</i> – It will be interesting to see how the DoD responds to this observation. The belief that the funds can’t be mixed extends to the personnel they support. As a result, contract staff who are hired on research protocols are told they cannot help with patient care and vice versa. Because clinical research and patient care often go hand in hand, this can create enormous logistical difficulties for investigators doing clinical research in MTFs and is off-putting in patients.</li> <li>• <i>“No funds directly allocated to research in military RDT&amp;E laboratories.”</i> If and when funding opportunities are clearly mapped out to programmatic needs (a core aspect of ‘requirements-driven’ research), this should help DoD laboratory staff focus on department priorities. However, some core funding is helpful to support innovative pilot studies and develop junior investigators. At USU, our Office of Vice President for Research has a funding line used for this purpose. In my opinion, the DoD hasn’t adequately considered the impact on career development of investing in intramural research. In addition to measuring products and associated knowledge products – DHB should consider advocating for measurement of faculty development as a metric in both the pre and post-award settings.</li> </ul>



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 2a:</b> The Services should develop a clear career and leadership path for officers with an interest in medical research with appropriate education, training, and opportunities to experience different aspects of medical research with the potential for eventual command opportunities at the medical research, development, test, and evaluation facilities.</p>	<ul style="list-style-type: none"><li>• <b>Board Discussion on 2/9/17:</b> The Board suggested that the Subcommittee request data on the gender and ethnic diversity of DoD health researchers and proposed creating a finding and recommendation based on these data.</li><li>• The Board discussed whether this recommendation would include research leadership opportunities at MTFs.</li><li>• <b>Comments:</b> It is important to recognize the contributions of women to research such as the CO at NHRC and the CO at DHCC, and to enhance the value of these positions as one moves up the military leadership ladder. Thus, a finding that could be part of the career development section, the proportion of women CO's in leadership of research-related or -focused units and the recommendation that this path continue to foster a focus on gender equity as professional development programs are developed.</li></ul>



Objectives, Findings, and Recommendations	Comments
	<ul style="list-style-type: none"><li>• <b>Comments:</b> There is significant variability in how the services develop military medical educators and researchers. The U.S. Air Force has long recognized an academic career vector, and works to develop an officer's skills along this pathway through positions of increasing responsibility and academic complexity to the rank of O-6. In 2016, the U.S. Navy formally recognized academics and research as specific credentials worthy of formal experience identifiers. As this system evolves, these identifiers may help with promotion and the retention of officers along specific academic career tracks. As the largest medical corps, the U.S. Army has traditionally had more officers on specific career trajectories devoted to education and research. But, recently this career track has not had a clear path to the rank of O-6. Although command of a research lab or chair of an academic department at USU should be considered a career pinnacle for academic officers, this view is not necessarily shared by MHS command staff. Ironically, uniformed chairs at West Point appear to be valued more highly by the line than leadership values uniformed chairs at USU. As a result, many Army physicians feel compelled to leave academics at mid-career to take on administrative or clinical leadership positions because they see this as the only way to advance.</li><li>• In all services, service-mandated reductions in force combined with the increased operational deployment tempo have made it very difficult to balance the need to fill clinical billets and MTF leadership roles, support units in deployed settings and maintain support for education and research. The stress this imposes has prompted the early separation of a number of academic physicians who have taken their hard-won educational and research skills to the civilian world. It may never happen, but the DoD should consider waiving the 30 year maximum service time frame for its most productive researchers.</li></ul>



Objectives, Findings, and Recommendations	Comments
	<p>•USU could help foster the recruitment and development of military health researchers in a variety of ways. For example: 1) each service (Army, Navy and Air Force) could allow USU to authorize 1-2 students per year to do a research year at the NIH or a military lab between their 3rd and 4th year. Ironically, while USU can decelerate struggling students for a year in order to help them get back on track, we lack the authority to offer our most promising students the option of adding a year to do mentored research at the NIH or another federal laboratory; 2) In addition, each service could direct us to recruit a small but carefully selected group of students to pursue an combined MD/PhD degree. If this course of action is taken, the services should put these graduates on a suitable career path during their subsequent residency, fellowship and career assignments.</p> <p>•Another important way to foster scholarship is to ensure that military GME programs, particularly in the largest MTFs, have a dedicated research development funds. This is properly noted in the report. Finally, the career progression of research-oriented military healthcare providers should be tracked and nurtured. USU is well positioned for this role.</p> <p>• <b>Comments:</b> Support. Narrative should convey this as a suggestion to the services; otherwise, it will tend to prolong the differences in research career development rather than establishing a significant common ground. Long term it encourages an alignment of research development to enable officers to cross over services either for expertise or other career enhancement.</p>



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 2b:</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.</p>	<ul style="list-style-type: none"> <li>• <b>Board Discussion on 2/9/17:</b> Members suggested the Subcommittee consider what type of metrics could be included in this recommendation and asked whether “military medical center” may be more appropriate than “MTF.”</li> <li>• Dr. Wayman Cheatham of the U.S. Navy Bureau of Medicine and Surgery added that the Center for Naval Analyses is conducting a review on how various health care organizations value research, to be released in August 2017 and offered that the Board may request for release of these data.</li> <li>• <b>Comments:</b> <i>“Performance evaluations of MTF commanders...”</i> Given the tradition of frequently rotating MTF commanders, it is difficult to see how one can influence their facility’s research output in such short spans of time.</li> <li>• <b>Comments:</b> Support. It is tied to 2a and 5c.</li> <li>• This goal of more research in the MTFs is attractive. The path suggested is running against services’ need to evaluate all commanders, whether at an MTF or “not” in the same manner. As written those falling in the “not” category are rates as commanders without access to research efforts. This could be a double standard. Consider a recommendation for a program oversight (recommendation 1a and 1e) where the Services and MTFs get rewarded by research dollars or further research opportunity. More and better research means more funding.</li> </ul>



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 2c:</b> The Military Health System should establish a relative value unit for medical research at the military treatment facilities.</p>	<ul style="list-style-type: none"> <li>• <b>Board Discussion on 2/9/17:</b> The group discussed the feasibility of creating a relative value unit (RVU) for research and whether the recommendation was too prescriptive.</li> <li>• The group also discussed creating protected time for research and the possibility of accounting for research activities in MHS GENESIS, the new electronic health record.</li> <li>• <b>Comments:</b> <i>“Establish an RVU for medical research.”</i> Given the pernicious effects of RVUs on provider morale and time allocation, I’d rather see the DHB question its utility in a system aligned to achieving the quadruple aim rather than generate fee-for-service revenue. If the DHB’s proposed solution is adopted, it would entrench the practice of RVU measurement rather than replace it with something better, such as the National Academies “Vital Signs” core metrics of health system performance: <a href="http://nationalacademies.org/HMD/reports/2015/vital-signs-core-metrics.aspx">http://nationalacademies.org/HMD/reports/2015/vital-signs-core-metrics.aspx</a>.</li> <li>• <b>Comments:</b> Support the concept of crediting effort with a metric recognized by the entire medical community.</li> </ul>
<p><b>Recommendation 2d:</b> The Services should enhance ways to 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.</p>	<ul style="list-style-type: none"> <li>• <b>Board Discussion on 2/9/17:</b> The Board asked the Subcommittee to consider emphasizing faculty and career development in this recommendation.</li> <li>• <b>Comments:</b> Support. There is a variable level of engagement by MTFs to encourage research. If 2b is achieved, then 2d follows.</li> <li>• MTFs ought to be and should be working on DoD research priorities. This can only be accomplished with a more enterprise oversight and management.</li> </ul>



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 2e:</b> The Services should recruit officers with medical research training and offer training opportunities (e.g., research fellowships) to those without such training who are interested in a research career path.</p>	<ul style="list-style-type: none"> <li>• <b>Board Discussion on 2/9/17:</b> The Board asked the Subcommittee to consider emphasizing faculty and career development in this recommendation.</li> <li>• <b>Comments:</b> “..offer research training opportunities (e.g., research fellowships).” This is a good idea, but to work these fellowships need to be properly staffed and supported by mentors. The fellows should be strategically placed in large military laboratories, USUS and/or MTFs where mentorship is robust, research opportunities are plentiful and affiliations with local agencies and academic partners (e.g., USU, NIH), and/or civilian academic partners are strong.</li> <li>• <b>Comments:</b> Support.</li> </ul>
<p><b>3. Determine how Department of Defense may facilitate more efficient initiation and conduct of high-quality Defense Health Program research without compromising safety or data protection standards.</b></p>	
<p><b>Finding 3:</b> 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. 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.</p>	



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 3:</b> The Department of Defense should establish several regional, tri-Service research infrastructure support centers under the Defense Health Agency within the military treatment facility system and require that anyone conducting human subjects research be affiliated with one of these centers. The centers should be used by all military treatment facilities within their designated region and provide the necessary competencies and oversight (e.g., those shown in Table 3 of Appendix C.6) to ensure high-quality, regulatory compliant, and safe research.</p>	<ul style="list-style-type: none"> <li>• <b>Board Discussion on 2/9/17:</b> The Board asked the Subcommittee to consider recommending additional funding for career development and time for mentoring.</li> <li>• They also discussed the possibility of creating Congressionally-directed not-for-profit partnerships or the establishment or use of private foundations to help facilitate research, highlighting formal memorandums of understanding established between the Department of Veterans Affairs and the academic community.</li> <li>• Dr. George Ludwig of U.S. Army Medical Research and Materiel Command indicated he had a presentation on a legislative change proposal to establish a foundation that the Subcommittee could reference.</li> <li>• <b>Comments:</b> <i>“The DoD should establish several regional, tri-Service research infrastructure support centers under the DHA...”</i> It’s not entirely clear why these centers should be regional and why they should be operated (as opposed to overseen) by DHA rather than an academic institution such as the Uniformed Services University. In my view, USU could play a valuable role in enabling this recommendation. We have stable core funding, strong affiliations with multiple NIH institutes as well as other federal and DoD research agencies, several well-established national or global research networks such as the Infectious Disease Clinical Research Program (IDCRP), the Center for Neuroscience and Regenerative Medicine (CNRM), Army STARRS and the Murtha Cancer Center, a robust faculty development program that supports military healthcare educators and researchers across the MHS, a Learning Resource Center and plans to establish a global distributed learning (DL) capability. In addition, USU has branch offices in San Antonio (to support our Southern Region MTFs &amp; faculty) and San Diego (to support our Western Region/Pacific MTFs &amp; faculty). In addition, it should be noted that USU holds the academic credentials and portfolios for all uniformed faculty throughout the MHS. This represents nearly all of the services’ top educators and researchers.</li> </ul>



Objectives, Findings, and Recommendations	Comments
	<ul style="list-style-type: none"> <li>• <b>Comments:</b> Support.</li> <li>• <b>Comments:</b> Insert the following Recommendation in response to Finding 3 on pg ~31:</li> <li>• Recommendation 3b: The Defense Health Agency needs to implement a harmonized T2 program to remove current system-wide barriers to collaboration in accordance with Department of Defense Instruction 5535.8 and the OASD(R&amp;E) memorandum of 1July2014 to Director, DHA, RDA. Additionally, a plan for patent support of any DHA inventions should be devised and considered.</li> </ul>
<p><b>4. Determine how Department of Defense may improve Institutional Review Board processes to facilitate more efficient approval of multicenter studies and clinical trials.</b></p>	
<p><b>Finding 4:</b> 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. As is current National Institutes of Health policy, a single Institutional Review Board of record is the most efficient way to streamline the approval of multi-center studies.</p>	<p><b>Comments:</b> <i>“The Institutional Review Board process is currently fragmented across the services.”</i> This is true and problematic. To add insult to injury for military medical researchers, the DoD recently switched, on short notice, from one electronic IRB system to another. The transition has been highly disruptive to DoD researchers and their projects – not unlike what a hospital staff might experience if it suddenly switched from an EHR system that worked to one that is extremely cumbersome and unreliable. I hope is that these problems will either be resolved soon, or the DHA will recognize that it acquired the wrong product and return to the other one. Lack of consistency in research administration is not only a problem across services, it is a problem across MTFs and even from one Director of Research Programs (DRP) to another. Again, frequent turnover of uniformed personnel ensures a permanent learning curve.</p>



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 4a:</b> The Department of Defense should 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.</p>	<ul style="list-style-type: none"> <li>• <b>Comments:</b> “[D]esignate the Director of DHA Research and Development Directorate as the Single IO for all DoD human subjects research.” This recommendation surprises me. Is the thinking that the Director of DHA R&amp;D would hold the title of IO, but delegate the task to a civilian with the requisite expertise in the oversight and management of human subjects research? DHA senior leaders are certainly smart and capable, but they typically reach the post after a highly varied career and hold the post for 2-3 years at most. IRB oversight requires significant experience. Perhaps if a true career path for uniformed military researchers is established, things will be different in the future.</li> <li>• <b>Comments:</b> Strongly support.</li> <li>• <b>Comments:</b> Would recommend keeping human subjects program responsibilities (oversight of IRBs) separate from J-9. Recommend increased coordination.</li> </ul>
<p><b>Recommendation 4b:</b> The Department of Defense should establish policies and procedures to require a single Institutional Review Board to serve as the Institutional Review Board of record for multi-center studies.</p>	<ul style="list-style-type: none"> <li>• <b>Comments:</b> “Require a single IRB to serve as the IRB of record for all multi-center studies.” Given the Uniformed Services University’s successful implementation of a nationwide IRB for the IDCRP, it might be a logical place to host the multicenter IRB. USU is explicitly tri-service, is supported by a stable group of civilian staff and faculty who work with its uniformed personnel and is affiliated with almost every MTF in the nation through its support of faculty development as well as undergraduate and graduate education.</li> <li>• <b>Comments:</b> Strongly support. This encourages MTF commitment to collaborative research, increase patient pool and therefore statistical power.</li> </ul>



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 4c:</b> The Department of Defense should consolidate Institutional Review Board functions at the regional tri-Service research infrastructure support centers envisioned in Recommendation 3 and ensure that they receive the adequate resources to carry out their role.</p>	<ul style="list-style-type: none"> <li>• <b>Comments:</b> <i>“The DoD should consolidate IRB functions at the regional tri-Service research infrastructure support centers envisioned in recommendation 3.”</i> As noted above, this recommendation could be efficiently met through a partnership between the DHA and USU, which has a strong presence in every major MTF and has senior leaders based in San Diego, San Antonio and Bethesda.</li> <li>• <b>Comments:</b> Support.</li> </ul>
<p><b>Recommendation 4d:</b> The Institutional Official should establish standardized metrics of performance for Department of Defense Institutional Review Boards and ensure compliance to those metrics.</p>	<ul style="list-style-type: none"> <li>• <b>Comments:</b> Support.</li> </ul>



Objectives, Findings, and Recommendations	Comments
<p><b>5. Determine cost-effective mechanisms to encourage more professionals to become engaged in medical research.</b></p>	<ul style="list-style-type: none"> <li>• <b>Comments:</b> USU’s authority to hire “administratively determined’ (AD) faculty members allow us to compete fairly effectively for civilian researchers. The AD option provide us with two major advantages over most federal research facilities: a) Up to certain limits, we can offer salaries at pay levels consistent with the AAMC specialty-specific medians for academic faculty, and b) We can hire AD faculty on either the tenure or non-tenure track. In my opinion, the AD option approach is preferable to GS hiring, since the latter has a lower pay scale and it is very difficult if not impossible to remove a GS researcher who doesn’t turn out. Unfortunately, USU is constrained by the same tight FTE cap put on other DoD agencies. If we could hire to budget rather than an arbitrary number of FTEs, we could assign more USU “billeted” faculty and staff to MTFs across the county to support the Military Medical Research enterprise.</li> <li>• Although many military medical officers aspire to an academic career (teaching and/or research), but the pathways to do this are limited. There is significant variability in how the three Services develop their military medical educators and researchers. One ready-made way to foster acquisition and refinement of research and teaching skills (if the Services support it) is through academic affiliation with USU, the Uniformed Services University of the Health Sciences. In contrast to most medical schools, which are geographically focused, Nearly 25% of the military medical manpower in the U.S. and worldwide holds a faculty appointment with USU. Our institutional affiliations extend to all major and most minor MTFs in the US as well as overseas facilities and research labs.</li> <li>• One interesting gap in career support not noted in your report is that civilian universities and research labs typically pay for the memberships of their researchers in important professional societies. The DoD does not.</li> </ul>



Objectives, Findings, and Recommendations	Comments
<p><b>Finding 5:</b> As noted under Findings 2 and 3, there is a lack of clear command support for medical research at the military treatment facilities; inadequate infrastructure support to conduct research at the military treatment facilities; and, often, no core funding for the actual research at the medical research, development, test, and evaluation facilities. These are essential elements of cost-effective research. In addition, the pay scales for civilian medical researchers are not comparable to either the private sector or other governmental agencies. 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.</p>	
<p><b>Recommendation 5a:</b> The Department of Defense must provide the necessary research infrastructure support to conduct research and instruct the commands to embrace medical research as an essential part of the mission of the Department of Defense.</p>	<p>• <b>Comments:</b> Support. Tied to the development of #2 recommendations.</p>
<p><b>Recommendation 5b:</b> The Department of Defense should 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.</p>	<p>• <b>Comments:</b> Support. Mission should be a component when considering mechanism such as Title 38 and Title 42.</p>



Objectives, Findings, and Recommendations	Comments
<b>Recommendation 5c:</b> Medical research must be viewed as a career track and competency with special pays for research analogous to other specialty fields.	• <b><u>Comments:</u></b> Support. Tied to 2a.



Objectives, Findings, and Recommendations	Comments
<p><b>6. Determine mechanisms to improve acknowledgment in public communications by other government agencies and industry of Department of Defense contributions to products it has funded or partially developed.</b></p>	<p>•<b>Comments:</b> The MHS does not have a robust public communications capability. Part of this is cultural – military professionals don’t boast, and most deflect credit to others. Part of it is financial – it is not a budgetary priority. The Henry M. Jackson Foundation could partially fill this gap, but it has not chosen to do so. Another third problem, not noted in the report, is that high-impact medical journals tend treat military health as a “niche” topic, even when the study findings are widely applicable to civilian populations. As a member of the NAM with more than 200 peer reviewed papers, many in NEJM and JAMA, I’ve found it is much harder to get editors interested in military health topics than studies involving VA or civilian patients. Fortunately, there have been a few notable papers on the impact of DoD medical research, in the past 6 months. I looked but didn’t see them in your bibliography, I encourage the DHB to mention them.</p> <p>• In 2016, the National Academy of Medicine released a major consensus report, entitled “A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury” Many current and retired military health researchers contributed to this report, and military trauma and emergency care research was prominently featured.  <a href="http://www.nationalacademies.org/hmd/Reports/2016/A-National-Trauma-Care-System-Integrating-Military-and-Civilian-Trauma-Systems.aspx">http://www.nationalacademies.org/hmd/Reports/2016/A-National-Trauma-Care-System-Integrating-Military-and-Civilian-Trauma-Systems.aspx</a></p> <p>• Shortly after this report was released. Dr. Donald Berwick, chair of the NAM Committee that wrote it, noted in a JAMA editorial entitled, “A National Trauma Care System to Achieve Zero Preventable Deaths After Injury: Recommendations From a National Academies of Sciences, Engineering, and Medicine Report” In it, he notes that “military medicine put the learning health system framework into practice before the Institute of Medicine described it.”  <a href="http://jamanetwork.com/journals/jama/fullarticle/2529582">http://jamanetwork.com/journals/jama/fullarticle/2529582</a></p>



Objectives, Findings, and Recommendations	Comments
	<ul style="list-style-type: none"> <li>• Last October, Col Todd Rasmussen published a Perspective entitled, “Wartime Lessons — Shaping a National Trauma Action Plan” (Attached to this document). A table included in this article lists “examples of knowledge or materiel solutions supported by or resulting from the Department of Defense Combat Casualty Care Research Program and the Military’s learning health system in trauma care.” In addition, the article notes that the DoD accounts for roughly 80% of federal spending on trauma care research. The DHB should strongly consider reprinting this table as an example of the value of military health research.  <a href="http://www.nejm.org/doi/full/10.1056/NEJMp1607636">http://www.nejm.org/doi/full/10.1056/NEJMp1607636</a></li> </ul>
<p><b>Finding 6:</b> The Department of Defense has an extraordinary history of accomplishments in medical research including confirmation of routes of transmission of infectious diseases such as typhoid fever and yellow fever, as well as development of anti-malarial agents. Most recently, they have been key contributors to combat casualty care research and emerging infectious diseases, such as Ebola. However, the majority of the public is unaware of this history and current accomplishments. There are a series of meetings that could facilitate communication of Department of Defense medical research successes and recruit Department of Defense investigators, such as the Military Health System Research Symposium and other professional meetings. However, current conference attendance restrictions impede the ability to do</p>	



Objectives, Findings, and Recommendations	Comments
so.	
<b>Recommendation 6a:</b> The Department of Defense should 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. This should be done in concert with appropriate press briefings.	<ul style="list-style-type: none"><li>• <b>Comments:</b> Great idea. Concur.</li><li>• <b>Comments:</b> Support.</li></ul>



Objectives, Findings, and Recommendations	Comments
<p><b>Recommendation 6b:</b> Department of Defense scientists should be allowed and encouraged to present their findings at national and international specialty and subspecialty meetings.</p>	<ul style="list-style-type: none"> <li>• <b>Comments:</b> The biggest barrier to getting DoD scientists to present their findings is not lack of encouragement or permission; its lack of support for travel. Currently, many MHS researchers use their annual leave to attend these meetings and pay for their trips out of pocket.</li> <li>• <b>Comments:</b> Support. Funding is the issue not the desire by the researchers to present. DoD should expand the opportunities to attend relevant scientific meetings to present their findings. Tied to 3, 4c and 5a regarding infrastructure to support research activities, manuscript preparation, protected time.</li> </ul>
<p><b>Recommendation 6c:</b> Department of Defense scientists should be expected to publish their findings in national, peer-reviewed journals in a timely manner, with appropriate acknowledgment of Department of Defense funding.</p>	<ul style="list-style-type: none"> <li>• <b>Comments:</b> We already do this at USU, but will do a quick audit to determine if DoD funding is explicitly noted on all papers.</li> <li>• <b>Comments:</b> Support. Same as 6b.</li> </ul>
<p><b>Recommendation 6d:</b> The Department of Defense should ensure broad distribution of the biennial report discussed in Recommendation 1b.</p>	<ul style="list-style-type: none"> <li>• <b>Comments:</b> Concur</li> <li>• <b>Comments:</b> Support.</li> </ul>



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