



Update for Defense Health Board: “Improving Defense Health Program Medical Research Processes”

6 August 2019



Defense Health Board Report:

Improving Defense Health Program Medical Research Processes



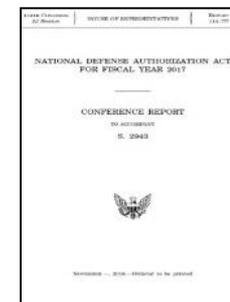
- In 2016, Acting USD(P&R) tasked the Defense Health Board (DHB) to provide recommendations to optimally support military medical professionals who oversee and conduct Defense Health Program (DHP) medical research. Specifically requested the DHB to:
 - Determine the major challenges that DoD investigators face in initiating, funding, attaining approval, conducting, and publishing DHP medical research; and
 - Determine cost-effective mechanisms to encourage more professionals to become engaged in research.

Major Changes: Military Health System and Defense Health Agency



- NDAA 2017, Directs DHA to assume Authority, Direction and Control of MTFs
 - Includes Clinical Investigations Programs (CIP) and the Human Research Protection Programs (HRPP)
- NDAA 2019, Strengthens DHA's role in the Military Health System
 - Section 711 (e) directs the establishment of new R&D organization within the DHA

NDAA 2017



Dec 2016

Directs DHA to assume Authority, Direction and Control of MTFs

NDAA 2019



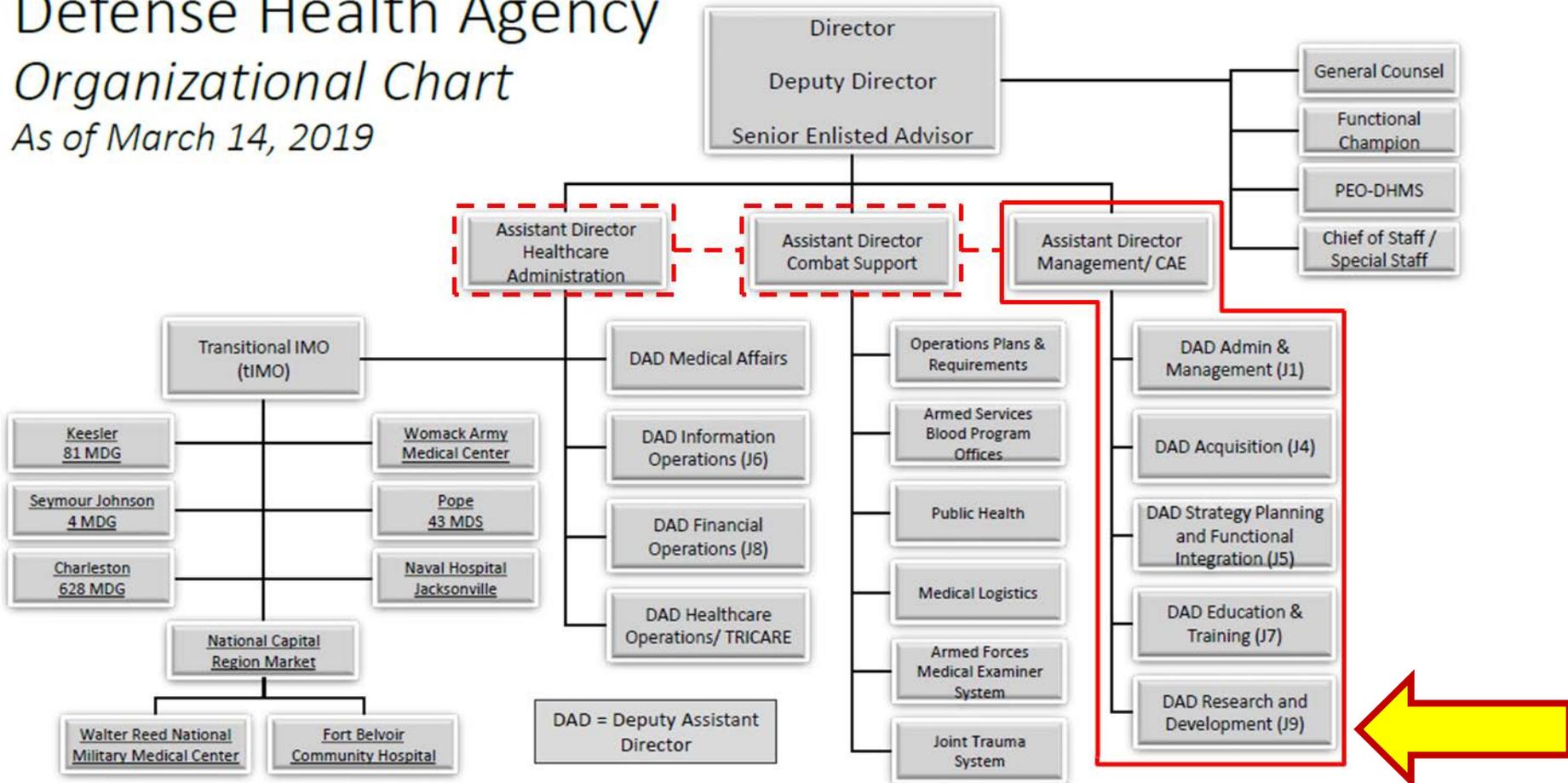
Aug 2018

Strengthens DHA's Role in MHS

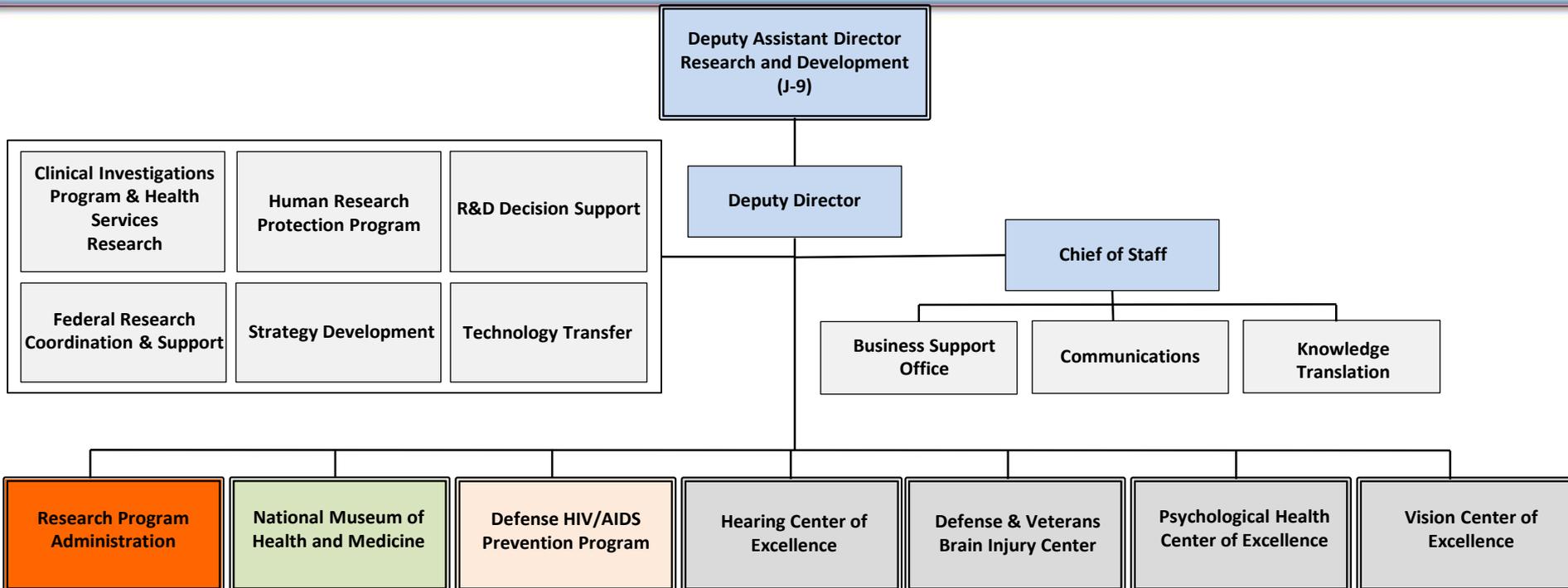
Defense Health Agency (DHA): Organization Chart



Defense Health Agency Organizational Chart As of March 14, 2019



DHA Research & Development (J-9): Organizational Chart



Key	
	J-9 Senior Leaders
	HQ Staff
	Research Portfolio Administration
	National Museum of Health and Medicine
	Defense HIV/AIDS Prevention Program
	Centers of Excellence

DHA Research & Development (J-9): Current Vision and Mission

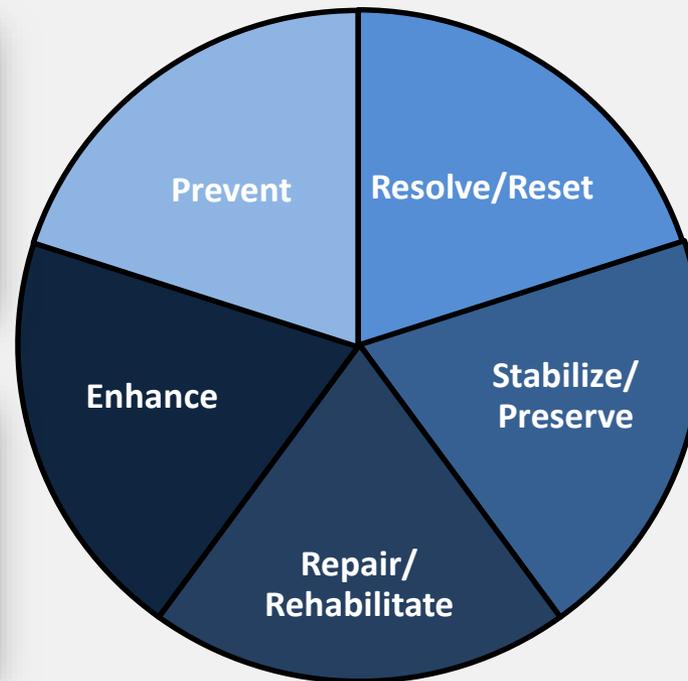


Vision

Bridging the future of military health and readiness

Mission

J-9 leads the discovery, development, and delivery of enhanced pathways to military health and readiness.



DHA Research & Development (J-9): Current Divisions



Defense HIV/AIDS Prevention Program

- Build capable military partners through military-specific, culturally focused HIV/AIDS cooperation and assistance.

Hearing Center of Excellence

- Optimize operational performance, heighten medical readiness, and enhance quality of life through collaborative leadership and advocacy for hearing and balance health initiatives.

National Museum of Health and Medicine

- Promote the science and history of military medicine—through innovative exhibits; educational programs; and scientific, historical, and medical research.

Psychological Health Center of Excellence

- Improve the lives of our nation's military beneficiaries by advancing excellence in psychological health care, readiness, and prevention of psychological health disorders.

Research Program Administration

- Champion innovative military medical research and development to meet the highest priority needs across the MHS.

Defense and Veterans Brain Injury Center

- Promotes innovative care from point of injury to reintegration for Service members, veterans, and their families to prevent and mitigate consequences of mild to severe traumatic brain injury.

Vision Center of Excellence

- Addresses the full scope of vision care including prevention, diagnosis, mitigation, treatment, research and rehabilitation of military eye injuries and diseases including visual dysfunctions related to traumatic brain injury (TBI)

Research & Development Reform: Defense Health Agency



- NDAA 2017 & 2019
- Impact of DHB report
 - This report, along with the DHA's maturation as an organization, has resulted in a series of efforts to institute changes and process improvement

Defense Health Board Report:

Overview of DoD Response



- Concurred or partially concurred with several of the recommendations
- Overall, concur the current state for managing and funding DHP should be improved
- For findings two and five, and their subsequent recommendations, we provided a non-concur since these actions do not fall under our purview

Defense Health Board Report:

Status of Recommendations



		NOT STARTED	POTENTIAL RISKS	ON TRACK/ COMPLETE
	RECOMMENDATION	CONCURRENCE	STATUS	
DHB 1(a)	DHA R&D Directorate (J-9) have direct oversight over all Defense Health Program (DHP) medical research.	Concur	<ul style="list-style-type: none"> • NDAA FY17 Section 702, CIP and HRPP • NDAA FY19 Section 711 (e), Consolidation of DoD Medical Research • NDAA FY19 Section 736, Strategic Medical Research Plan 	
DHB 1(b)	J-9 issue a comprehensive biennial report on the status of DoD conducted medical research.	Concur	<ul style="list-style-type: none"> • Not completed 	
DHB 1(c)	J-9 ensure integrated program plans (IPP) take into account all DHP medical research.	Concur	<ul style="list-style-type: none"> • NDAA FY19 Section 736, Strategic Medical Research Plan • Traumatic Brain Injury Strategy Plan • DHA Research & Development Procedural Instruction 	
DHB 1(d)	J-9 conduct periodic, external scientific reviews of Joint Program Committees' (JPC) IPPs.	Concur	<ul style="list-style-type: none"> • Not completed 	

Defense Health Board Report:

Status of Recommendations



		NOT STARTED	POTENTIAL RISKS	ON TRACK/ COMPLETE
	RECOMMENDATION	CONCURRENCE	STATUS	
DHB 1(e)	J-9 ensure all non-classified DHP RDT&E funded research entered into Federal RePORTER.	Concur	<ul style="list-style-type: none"> Enterprise portfolio solution Increased financial visibility Project level information 	
DHB 1(f)	J-9 ensure all DHP medical research clinical trials are listed in ClinicalTrials.gov.		<ul style="list-style-type: none"> Completed 	
DHB 1(g)	J-9 create a database provides visibility of all DHP medical research but, not limited to DHP-funded research, line funded research and other DoD-funded research.	Partially Concur	<ul style="list-style-type: none"> Enterprise portfolio solution Increased financial visibility Project level information Common financial system for DHA & Army 	

Defense Health Board Report: Status of Recommendations



		NOT STARTED	POTENTIAL RISKS	ON TRACK/ COMPLETE
	RECOMMENDATION	CONCURRENCE	STATUS	
DHB 2(a)	The Services develop a clear recruitment strategy and career leadership.	Non-Concur	<ul style="list-style-type: none"> No action 	N/A
DHB 2(b)	The Services include in performance evaluation of MTF commanders. Evaluation include impact of research on warfighter.	Partially Concur	<ul style="list-style-type: none"> No action 	N/A
DHB 2(c)	MHS should establish a relative value unit for medical research at MTF or prorate the number RVUs required for individuals who also conduct research.	Non-Concur	<ul style="list-style-type: none"> No action 	N/A
DHB 2(d)	The Services use DHP RDT&E to support medical research at MTFs and support a core amount research at RDT&E facilities.	Concur	<ul style="list-style-type: none"> NDA FY17 Section 702, CIP Evaluating a Regional Model 	

Defense Health Board Report:

Status of Recommendations



			NOT STARTED	POTENTIAL RISKS	ON TRACK/ COMPLETE
	RECOMMENDATION	CONCURRENCE	STATUS		
DHB 3(a)	DHA establish regional, tri-Service research infrastructure support centers.	Partially Concur	<ul style="list-style-type: none"> NDA FY17 Section 702, CIP Evaluating a Regional Model 		
DHB 3(b)	DHA implement a harmonized technology transfer (T2) program.	Concur	<ul style="list-style-type: none"> T2 Office established T2 PI published on 20 JUN 2019. 		
DHB 4(a)	DHA designate J-9 Director Institutional Official (IO) for all DoD human subjects research to oversee all DoD Institutional Review Boards (IRBs).	Partially Concur	<ul style="list-style-type: none"> NDA FY17 Section 702, HRRP HRRP transferred to DHA J-9 1 OCT 2019 IOC 1 OCT 2020 FOC 		
DHB 4(b)	DHA consolidate IRB functions at the regional, tri-Service research infrastructure support centers.	Concur	<ul style="list-style-type: none"> After all the Service hospital IRBs are transferred to DHA in FY20, DHA will implement plans to establish a single IRB with 4 or 5 regional panels. 		
DHB 4(c)	DHA establish policies and procedures to require a single IRB to serve as IRB of record	Partially Concur	<ul style="list-style-type: none"> Single IRB to be established NLT 1 OCT 2021 		

Defense Health Board Report:

Status of Recommendations



			NOT STARTED	POTENTIAL RISKS	ON TRACK/ COMPLETE
	RECOMMENDATION	CONCURRENCE	STATUS		
DHB 4(d)	DHA instruct IO to establish standardized metrics of performance for IRBs.	Partially Concur	<ul style="list-style-type: none"> Developing a Component Management Plan 		
DHA 4(e)	DHA ensure each protocol undergoes a review and approval by relevant DoD IRB.	Concur	<ul style="list-style-type: none"> Completed 		
DHB 5(a)	DoD provide research infrastructure support and core funding to conduct research and instruct MHS commands to embrace research as part of mission.	Concur	<ul style="list-style-type: none"> NDA FY17 Section 702, CIP Evaluating a Regional Model ASD(HA) should include medical research as part of future strategic plans for MHS 		
DHB 5(b)	DoD active duty career track and competency with special pays analogous to specialty fields.	Non-Concur	<ul style="list-style-type: none"> No action 		N/A

Defense Health Board Report: Status of Recommendations



			NOT STARTED	POTENTIAL RISKS	ON TRACK/ COMPLETE
	RECOMMENDATION	CONCURRENCE	STATUS		
DHB 5(c)	DoD pursue the authority to provide pay incentives for civilian health professionals engages in military medical research.	Non-Concur	<ul style="list-style-type: none"> No action 		N/A
DHB 6(a)	DoD ensure broad distribution of the biennial report discussed in Recommendation 1(b).	Concur	<ul style="list-style-type: none"> Not completed 		
DHB 6(b)	DoD ensure the Military Health System Research Symposium (MHSRS) contains a section on accomplishments of past year.	Concur	<ul style="list-style-type: none"> A section was added to MHSRS Public Affairs staff involved in the MHSRS and in web-publishing of recent accomplishments. 		
DHB 6(c)	DoD allow, encourage, and fund investigators to present at meetings.	Partially Concur	<ul style="list-style-type: none"> Ongoing 		
DHB 6(d)	DoD indicate investigators expected to publish their findings.	Partially Concur	<ul style="list-style-type: none"> J-9 includes language in the DHP RDT&E granting and contracting language 		

Defense Health Board Report:

Next Steps



- DHA J-9 will proceed to implement changes, as necessary, to improve the DHP medical research and CIP
- DHA J-9 continues to look ahead for additional opportunities to improve the operation of the DoD Medical R&D enterprise during this time of reform



QUESTIONS?