Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0601101DHA *I In-House Laboratory Independent Research (ILIR)*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	9.510	4.330	2.653	2.879	-	2.879	3.687	4.013	4.093	4.175	Continuing	Continuing
010A: *CSI - Congressional Special Interests*	0.315	1.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
240A: *Infectious Disease (USUHS)*	1.286	0.401	0.390	0.421	-	0.421	0.480	0.490	0.500	0.510	Continuing	Continuing
240B: *Military Operational Medicine (USUHS)*	3.946	1.230	1.154	1.251	-	1.251	1.479	1.509	1.539	1.570	Continuing	Continuing
240C: *Combat Casualty Care (USUHS)*	3.963	1.699	1.109	1.207	-	1.207	1.728	2.014	2.054	2.095	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services of the Health Sciences (USUHS), this program element supports basic medical research at the Uniformed Services University of the Health Sciences (USUHS). It facilitates the recruitment and retention of faculty; supports unique research training for military medical students and resident fellows; and allows the University's faculty researchers to collect pilot data towards military relevant medical research projects in order to secure research funds from extramural sources (estimated $180 million annually). Approximately 48 intramural research projects are active each year, including 18 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the knowledge base intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs. USU enriches the training of the next generation of physicians/scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system.

The ILIR program at USUHS is designed to answer fundamental questions of importance to the military medical mission of the Department of Defense in the areas of Combat Casualty Care, Infectious Diseases, Military Operational Medicine, and Chemical, Biological, and Radiologic Defense. The portfolio of research projects will vary annually because this research is investigator-initiated. Examples of typical research efforts are detailed in R-2a.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0601101DHA / *In-House Laboratory Independent Research (ILIR)*

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	3.599	2.653	2.879	-	2.879
Current President's Budget	4.330	2.653	2.879	-	2.879
Total Adjustments	0.731	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	1.000	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.269	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 010A: *CSI - Congressional Special Interests*		
Congressional Add: *468A – Program Increase: Restore Core Research Funding Reduction (USUHS)*	1.000	-
Congressional Add Subtotals for Project: 010A	1.000	-
Congressional Add Totals for all Projects	1.000	-

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601101-In-House Laboratory Independent Research (-$0.269 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$0.269 million).

FY 2016: Restores core research funding to the DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (+$1.000 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601101-In-House Laboratory Independent Research (-$1.000 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+$1.000 million).

FY 2018: No Change.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601101DHA / *In-House Laboratory Independent Research (ILIR)*	Project (Number/Name) 010A / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
010A: *CSI - Congressional Special Interests*	0.315	1.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY15 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) - In-House Laboratory Independent Research (ILIR). Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 468A – Program Increase: Restore Core Research Funding Reduction (USUHS)	1.000	-
FY 2016 Accomplishments: FY 2016 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the In-House Laboratory Independent Research (ILIR) Program Element (PE) - 0601101.		
Congressional Adds Subtotals	1.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601101DHA / *In-House Laboratory Independent Research (ILIR)*	Project (Number/Name) 240A / *Infectious Disease (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
240A: *Infectious Disease (USUHS)*	1.286	0.401	0.390	0.421	-	0.421	0.480	0.490	0.500	0.510	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services of the Health Sciences (USUHS), this program element supports basic medical research at the Uniformed Services University of the Health Sciences (USUHS). It facilitates the recruitment and retention of faculty; supports unique research training for military medical students and resident fellows; and allows the University's faculty researchers to collect pilot data towards military relevant medical research projects in order to secure research funds from extramural sources (estimated $180 million annually). Approximately 48 intramural research projects are active each year, including 18 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the knowledge base intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs. USU enriches the training of the next generation of physicians/scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system.

The ILIR program at USUHS is designed to answer fundamental questions of importance to the military medical mission of the Department of Defense in the areas of Combat Casualty Care, Infectious Diseases, Military Operational Medicine, and Chemical, Biological, and Radiologic Defense. The portfolio of research projects will vary annually because this research is investigator-initiated. Examples of typical research efforts are detailed in R-2a.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Infectious Disease	0.401	0.390	0.421
Description: Infectious Diseases: Immunology and molecular biology of bacterial, viral and parasitic disease threats to military operations. These threats include Bartonella bacilliformis, Clostridium difficile, Escherichia coli and their Shiga toxins, Henipaviruses (Hendra & Nipah), Cedar Virus, Hepatitis A, Helicobacter pylori, HIV, HTLV-1, Leishmaniasis, Litomosoides sigmodontis, Malaria, Neisseria gonorrhoeae, Shigella spp., Streptococcus, and Methicillin-resistant Staphylococcus aureus (MRSA).			
FY 2016 Accomplishments: Representative projects include the following: determination of the factors responsible for maintaining and driving the immune response against helminth, such as Litomosoides sigmodontis, (parasitic worm) infections eventually leading to effective vaccines against these infections as well as a better understanding of food allergies; characterization of the alternative energy-generating pathways in C. difficile as a potential target to prevent the transmission and recurrence of Clostridium difficile infection (CDI), the leading cause of nosocomial, antibiotic-associated diarrhea; classifying the effect of neonatal tissue-dependent immunity on respiratory syncytial virus; investigation of skin and soft tissue infections (SSTI) in the military population, generally caused by community-associated methicillin-resistant Staphylococcus aureus (CA-MRSA), towards the development of novel prevention and treatment strategies; investigation of the Henipaviruses and their bat hosts towards the development of novel intervention and			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0601101DHA / *In-House Laboratory Independent Research (ILIR)*	**Project (Number/Name)** 240A / *Infectious Disease (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
vaccine strategies; analysis of the entry and egress of Cedar Virus a new species of Henipavirus; development of a cutaneous Leishmaniasis vaccine to prevent parasitic infection; investigation of the epidemiology of Malaria in asymptomatic HIV patients; elucidation of the natural transmission of Bartonella bacilliformis by the sand fly towards disease prevention and control; analysis of genetic factors resulting in colonization of the host intestinal tract by Escherichia coli O157:H7, the most common infectious cause of bloody diarrhea & hemorrhagic colitis; understand how antibiotic resistance mutations in Neisseria gonorrhoeae (Gc), whose infections occur at a high incidence throughout the world and in the United States and U.S. military, may influence the spread of resistant strains which subsequently threatens control methods as well as our capacity to limit the spread of human immunodeficiency virus; design of a new class of anti-viral therapeutics (HAIVA prep) for critical conditions like acute pulmonary infection (with different types of flu viruses), and for vaccination purposes in imminent flu endemics; and the health behaviors and deployment factors that are associated with acquisition of sexually transmitted diseases (STDs). These projects will support the essential military mission by advancing our understanding of both the transmission and the internal mechanisms of a spectrum of pernicious and/or common diseases that may be faced by warfighters both at home and abroad. In turn, that understanding opens avenues to better control, diagnosis, and treatment of both natural and manmade biological threats. ***FY 2017 Plans:*** A high priority research project involving antibiotic resistant Neisseria gonorrhea strains has been initiated. The goal of this project is develop of a novel therapy for gonorrhea that can be used with currently licensed antibiotics to increase antibiotic effectiveness against sensitive and resistant strains, reduce the risk of antibiotic resistance mutations, and limit inflammation. Investigation continues for infectious diseases that impact soldiers from the standpoint of lost “man-days” to death. Since infectious disease can severely hamper combat readiness and effectiveness, there will be continued efforts on diagnosis and treatment of those naturally occurring infectious diseases that can affect the war fighter by further development of vaccines, drugs, and diagnostic tools. ***FY 2018 Plans:*** Efforts will continue within the Infectious Disease research area in FY 2018. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.			
Accomplishments/Planned Programs Subtotals	0.401	0.390	0.421

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0601101DHA / *In-House Laboratory Independent Research (ILIR)*	**Project (Number/Name)** 240A / *Infectious Disease (USUHS)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601101DHA / *In-House Laboratory Independent Research (ILIR)*	Project (Number/Name) 240B / *Military Operational Medicine (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
240B: *Military Operational Medicine (USUHS)*	3.946	1.230	1.154	1.251	-	1.251	1.479	1.509	1.539	1.570	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services of the Health Sciences (USUHS), this program element supports basic medical research at the Uniformed Services University of the Health Sciences (USUHS). It facilitates the recruitment and retention of faculty; supports unique research training for military medical students and resident fellows; and allows the University's faculty researchers to collect pilot data towards military relevant medical research projects in order to secure research funds from extramural sources (estimated $180 million annually). Approximately 48 intramural research projects are active each year, including 18 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the knowledge base intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs. USU enriches the training of the next generation of physicians/scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system.

The ILIR program at USUHS is designed to answer fundamental questions of importance to the military medical mission of the Department of Defense in the areas of Combat Casualty Care, Infectious Diseases, Military Operational Medicine, and Chemical, Biological, and Radiologic Defense. The portfolio of research projects will vary annually because this research is investigator-initiated. Examples of typical research efforts are detailed in R-2a.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Military Operational Medicine	1.230	1.154	1.251
Description: Military Operational Medicine: Sustainment of individual performance; mapping and managing deployment and operational stressors; cognitive enhancement; use of dietary and nutritional supplements and military and medical training readiness. ***FY 2016 Accomplishments:*** Representative projects will include the following: refinement of a single item post traumatic stress disorder (PTSD) screening tool for use in the DOD Primary Care system; understanding and attenuating deleterious effects of tobacco, alcohol, stress and their interactions upon military personnel; forecasting levels of full or threshold PTSD, depression, health and alcohol problems within the military population; determination of the unique proteomic signature for the diagnosis and assessment of the neuro-immune response to traumatic brain injury (TBI) towards early assessment of the disease in the military and veteran population; understanding the determinants of health promoting behaviors towards preventing obesity in both active duty military and their family members; identifying signaling pathways that control satiety and dietary triggers towards prevention of obesity; implementation of a neuromuscular routine that minimizes musculoskeletal injury in military academy cadets; study the relationship between previous ankle injury, a common event in military populations, and future serious injury, such as ACL injury as musculoskeletal injury (MSK-1) is the #1 cause of lost and limited duty in the U.S. military; evaluation of suicidal behaviors			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0601101DHA / *In-House Laboratory Independent Research (ILIR)*	**Project (Number/Name)** 240B / *Military Operational Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
within recent suicide deaths of active duty service members to aid in identification and prevention efforts; study of load and dual tasking interaction with executive function and mobility; determination of the psychosocial and biomedical risks and protective factors for heart failure and ischemia within the military and veteran population; and the determination of non-invasive neurological biomarkers for heat intolerance using in vivo Magnetic Resonance Imaging (MRI) and Spectroscopy (MRS). These studies support the essential military mission by enhancing and protecting the health, performance and fitness of soldiers throughout the deployment cycle. These studies strive to increase our understanding of and ability to manipulate the physiological mechanisms of stress and immunity, human sleep and seasonal cycles, and neurological changes necessary for short- and long-term memory. Their discoveries should enable warfighters to stay awake longer with fewer detriments to performance; lead to better strategies for enhancing and preserving memory and reasoning capabilities under battle conditions; help understand and ultimately prevent and treat neuropsychiatric illnesses such as depression and PTSD; and assist deployed troops and their families better prepare for and contend with common, significant stressors related to the deployment cycle. ***FY 2017 Plans:*** A new high priority research project was initiated studying the epigenetic regulation of adult neurogenesis to identify novel neural stem/progenitor cell pathways for therapeutic targeting in the development of neuroregenerative therapies to treat brain injury. Our efforts will concentrate on biomedical solutions that protect and enhance the health, performance, and fitness of our soldiers. Our focus will continue to be to understand stress as it is related to performance and health. We will also study performance in environmental extremes. Our goal is to lay the ground work that will establish platforms that build biomedical products and solutions that mitigate risk to soldiers and protect them from “head to toe” both on the battlefield and at home. ***FY 2018 Plans:*** Efforts will continue within the Military Operational Medicine research area in FY 2018. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.			
Accomplishments/Planned Programs Subtotals	1.230	1.154	1.251

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0601101DHA / *In-House Laboratory Independent Research (ILIR)*	**Project (Number/Name)** 240B / *Military Operational Medicine (USUHS)*

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0601101DHA / *In-House Laboratory Independent Research (ILIR)*	**Project (Number/Name)** 240C / *Combat Casualty Care (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
240C: *Combat Casualty Care (USUHS)*	3.963	1.699	1.109	1.207	-	1.207	1.728	2.014	2.054	2.095	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services of the Health Sciences (USUHS), this program element supports basic medical research at the Uniformed Services University of the Health Sciences (USUHS). It facilitates the recruitment and retention of faculty; supports unique research training for military medical students and resident fellows; and allows the University's faculty researchers to collect pilot data towards military relevant medical research projects in order to secure research funds from extramural sources (estimated $180 million annually). Approximately 48 intramural research projects are active each year, including 18 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the knowledge base intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs. USU enriches the training of the next generation of physicians/scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system.

The ILIR program at USUHS is designed to answer fundamental questions of importance to the military medical mission of the Department of Defense in the areas of Combat Casualty Care, Infectious Diseases, Military Operational Medicine, and Chemical, Biological, and Radiologic Defense. The portfolio of research projects will vary annually because this research is investigator-initiated. Examples of typical research efforts are detailed in R-2a.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Combat Casualty Care	1.699	1.109	1.207
Description: Combat Casualty Care: regenerative medicine, rehabilitation, neurological, limb loss, pain management, readiness, resilience			
FY 2016 Accomplishments: Bridging tissue gaps in the periphery following injury or surgery; guiding the regeneration of axons to neural-prosthetic interfaces following amputation, and; inhibiting axon extension following excision of neuromas. These studies support the military mission by providing cutting edge research that helps combat injured service members following orthopedic and neurological trauma.			
FY 2017 Plans: A new early career investigator award was initiated to investigate drug-induced arrhythmias with the goal of improving the safety profile of those drugs increasingly used to treat pathological conditions such as cardiac hypertrophy or hypercholesterolemia.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0601101DHA / *In-House Laboratory Independent Research (ILIR)*	**Project (Number/Name)** 240C / *Combat Casualty Care (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Our efforts will concentrate on diagnosis and treatment for our wounded warriors to reduce mortality and morbidity resulting from injuries on the battlefield. We will study physical and biological determinants of brain injury and post-traumatic stress disorder. In addition, we will also focus on rehabilitation for amputees and pain management. Our goal is to understand how to best care for soldiers who have suffered any type of physical or mental traumatic injury in the field. ***FY 2018 Plans:*** Efforts will continue within the Combat Casualty Care research area in FY 2018. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.			
Accomplishments/Planned Programs Subtotals	1.699	1.109	1.207

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0601117DHA *I Basic Operational Medical Research Sciences*

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
Total Program Element	19.087	9.002	6.444	6.917	-	6.917	7.699	8.608	8.913	9.091	Continuing	Continuing
100A: *CSI - Congressional Special Interests*	3.815	2.161	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
371A: *GDF-Basic Operational Medical Research Sciences*	15.272	6.841	6.444	6.917	-	6.917	7.699	8.608	8.913	9.091	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Basic Operational Medical Research Sciences: This program element (PE) provides support for basic medical research directed toward greater knowledge and understanding of the fundamental principles of science and medicine that are relevant to the improvement of Force Health Protection. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of Department of Defense DoD and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research and Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include military infectious diseases (JPC-2), military operational medicine (JPC-5), and combat casualty care (JPC-6). Funds in this PE are for basic research that promises to provide important new approaches to complex military medical problems. As the research efforts mature, the most promising efforts will transition to applied research (PE 0602115) or technology development (PE 0603115) funding.

In FY 2016, Congressional Special Interest (CSI) funds were provided for Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0601117DHA *I Basic Operational Medical Research Sciences*

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	7.397	6.444	6.917	-	6.917
Current President's Budget	9.002	6.444	6.917	-	6.917
Total Adjustments	1.605	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	2.161	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.556	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 100A: *CSI - Congressional Special Interests*		
Congressional Add: *461A – Program Increase: Restore Core Research Funding Reduction (Army)*	2.161	-
Congressional Add Subtotals for Project: 100A	2.161	-
Congressional Add Totals for all Projects	2.161	-

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-$0.556 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$0.556 million).

FY 2016: Restore core research funding to the DHP RDT&E, PE 06011117-Basic Operational Medical Research Sciences (+$2.161 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-$1.161 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+$1.161 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-$1.812 million) to DHP RDT&E, PE 0603115-Medical Technology Development for Breast, Gynecological and Prostate Cancer Centers of Excellence (+$1.812 million).

FY 2018: No change.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601117DHA / *Basic Operational Medical Research Sciences*	Project (Number/Name) 100A / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
100A: *CSI - Congressional Special Interests*	3.815	2.161	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2016 Defense Health Program (DHP) Congressional Special Interest (CSI) funding was directed toward restoration of core research initiatives in Program Element (PE) 0601117 - Basic Operational Medical Research Sciences. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 461A – Program Increase: Restore Core Research Funding Reduction (Army)	2.161	-
FY 2016 Accomplishments: This CSI initiative was directed toward FY 2016 DHP core research initiatives in PE 0601117. Funds supported basic research in military operational medicine and radiation health effects (Project 371A).		
Congressional Adds Subtotals	2.161	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601117DHA / *Basic Operational Medical Research Sciences*	Project (Number/Name) 371A / *GDF-Basic Operational Medical Research Sciences*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
371A: *GDF-Basic Operational Medical Research Sciences*	15.272	6.841	6.444	6.917	-	6.917	7.699	8.608	8.913	9.091	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Basic Operational Medical Research Sciences: Basic research described here focuses on enhancement of knowledge to support capabilities identified through the Joint Capabilities Integration and Development System process and sustainment of Department of Defense and multi-agency priority investments in science, technology, research, and development as stated in the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, and the National Strategy for Combating Antibiotic Resistance. This project supports basic research managed by the Joint Program Committees (JPCs) in the following areas: 1- Military Infectious Diseases basic research develops protection and treatment products for military relevant infectious diseases. 2- Military Operational Medicine basic research focuses on the development of medical countermeasures against operational stressors, prevention of physical and psychological injuries during training and operations, and maximizing the health, performance and fitness of Service members. 3- Combat Casualty Care basic research focuses on optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through en route and facility care.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Project 371 GDF – Basic Operational Medical Research Sciences	6.841	6.444	6.917
Description: Provide support for basic medical research directed toward attaining greater knowledge and understanding of fundamental principles of science and medicine relevant to the improvement of medical care in operationally relevant environments.			
FY 2016 Accomplishments: Military infectious diseases research supported basic research laboratory studies in bacterial diseases prevention, treatment, and management to develop antibacterial agents targeting biofilms and multi-drug resistant organisms (MDROs), and host and microbial biomarkers for early detection of infection. Outcomes from FY 2015-16 laboratory studies identified bacterial targets for prevention/treatment of diseases caused by bacterial agents. These studies aligned with the National Strategy for Combating Antibiotic Resistance. Military operational medicine research identified mechanisms and characterized behavioral effects in small animal models resulting from low level repeated blast exposure, characterized the biomechanical responses of brain tissue resulting from direct transmission of blast waves through the skull using computational modeling that will guide the development of interventions for mitigating blast-induced brain injury. Started studies to understand brain mechanisms associated with substance abuse problems that affect adult decision making and behavioral health. Began studies to examine the relationship of pre-accession factors such as personal mental health, familial mental health, and factors promoting resilience both with self-reported, and			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0601117DHA / *Basic Operational Medical Research Sciences*	**Project (Number/Name)** 371A / *GDF-Basic Operational Medical Research Sciences*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
official post-deployment mental diagnoses after high-conflict deployments. Started studies to identify gender-specific factors that impact military task performance, defined minimal physical requirements for entry into physically demanding military occupations. Investigated applications of novel interventions and their neurobiological impact via animal models to evaluate effectiveness in treating PTSD symptoms. Conducted basic studies to define medical standards for noise injury criteria, and identified novel interventions to promote sleep quality and nonpharmacological approaches to reduce the need for sleep in order to sustain Warfighter readiness. Studied the effects of inadequate nutrition on gut microbiota composition and function. Studied biomarkers of toxicity to complex chemical mixtures and particulates using an in vitro model.			
FY 2017 Plans: Military infectious diseases research continues to support multi-year basic research laboratory studies in bacterial diseases prevention, treatment, and management in discovery and development of antibacterial agents for biofilms and multi-drug resistant organisms (MDROs, detection of MDROs, and biomarkers. successful approaches are being selected for continued funding. New studies are being initiated to address the remaining gaps related to infection caused by MDROs. These studies support the National Strategy for Combating Antibiotic Resistance. Military operational medicine research is characterizing the biomechanical responses of brain tissue in animal models due to the indirect mechanism of blast waves (through the vasculature) using computational modeling that guides the development of interventions for mitigating blast-induced brain injury. Conducting research to identify the role of individual and unit climate factors on aggression. Beginning studies to understand the basic mechanisms underlying psychological resilience to inform potential future intervention and assessment work. Performing epidemiological studies to identify the nature of the substance abuse problem in the military and possible unique contributing and protective factors. Continuing PTSD research on genetic vulnerabilities, disease models and mechanisms, and identification of intervention targets for pharmacologic treatment approaches. Establishing mechanisms of electrical stimulation of the brain on wakefulness and cognitive processes. Identifying physiological factors that may affect the performance of female Warriors. Combat casualty care basic research is identifying the molecular and cellular mechanisms involved in abnormal bleeding due to coagulopathy of trauma that occurs following severe trauma. These findings are used to generate diagnostic and therapeutic targets for further development. The Systems Biology Program in coagulopathy of trauma is completing. Focus is shifting toward exploiting findings to develop specific diagnostics and therapeutics for coagulopathy of trauma.			
FY 2018 Plans: Military infectious diseases research will continue to support multi-year basic research studies in bacterial diseases for the prevention, treatment and management in discovery and development of antibacterial agents for biofilms and multi-drug resistant organisms (MDROs), detection of MDROs, and biomarkers. Successful approaches will continue to be selected for funding.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0601117DHA / *Basic Operational Medical Research Sciences*	**Project (Number/Name)** 371A / *GDF-Basic Operational Medical Research Sciences*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
New studies will continue to be initiated to address the remaining gaps related to infection caused by MDROs. These studies will support the National Strategy for Combating Antibiotic Resistance. Military operational medicine research will continue to characterize the biomechanical responses of brain tissue in animal models due to the indirect mechanism of blast waves (through the vasculature) that will guide the development of interventions for mitigating blast-induced brain injury. Will continue to define the role of individual and unit climate factors on aggression. Will begin to define linkages between identified genetic markers and individual performance or health risks. Will continue studies aimed at understanding the basic mechanisms underlying psychological resilience to inform potential future intervention and assessment work. Will continue epidemiological studies to identify the nature of the substance abuse problem in the military and possible unique contributing and protective factors. Will conduct research to identify candidate targets and neurological systems for treatment and diagnostic indicators of PTSD. Will define solutions to prevent, mitigate and/or recover from fatigue after electrical brain stimulation. Will identify physical, physiological and psychosocial factors that may differentially impact the performance of female versus male Service members and gender-based susceptibility to musculoskeletal injury. Will establish mechanisms of molecular changes in the brain following exposure to inhaled toxicants. Combat casualty care will focus on developing an understanding of associated pathophysiologic (functional changes associated with injury) mechanisms using advanced hemostatic and resuscitation approaches in prolonged field care scenarios when evacuation is delayed.			
Accomplishments/Planned Programs Subtotals	6.841	6.444	6.917

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Research is evaluated through in-progress reviews, Defense Health Program-sponsored review and analysis meetings, quarterly and annual status reports, and progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. The benchmark performance metric for transition of research conducted with basic science funding is the attainment of a maturity level that is typical of Technology Readiness Level 2 or the equivalent for knowledge products.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0602115DHA *I Applied Biomedical Technology*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	245.770	64.974	57.275	63.550	-	63.550	73.654	82.883	84.408	86.096	Continuing	Continuing
200A: *Congressional Special Interests*	96.186	11.071	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
246A: *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	0.000	2.913	2.860	2.142	-	2.142	1.857	1.949	1.989	2.029	Continuing	Continuing
306B: *Advanced Diagnostics & Therapeutics Research & Development (AF)*	9.620	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
306C: *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	0.000	1.728	1.757	1.987	-	1.987	2.025	2.066	2.107	2.149	Continuing	Continuing
306D: *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	0.000	1.728	1.758	1.988	-	1.988	2.026	2.066	2.108	2.150	Continuing	Continuing
372A: *GDF Applied Biomedical Technology*	125.005	40.072	43.462	49.639	-	49.639	58.724	67.148	68.357	69.724	Continuing	Continuing
447A: *Military HIV Research Program (Army)*	14.959	7.462	7.438	7.794	-	7.794	9.022	9.654	9.847	10.044	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Applied Biomedical Technology: This program element (PE) provides applied research funding to refine concepts and ideas into potential solutions for military health and performance problems, with a view toward evaluating technical feasibility. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of DoD Department of Defense and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0602115DHA *I Applied Biomedical Technology*

state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research & Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, radiation health effects, and clinical and rehabilitative medicine. Funds in the PE support studies and investigations leading to candidate solutions that may involve use of animal models for testing in preparation for initial human testing. As research efforts mature, the most promising efforts will transition to technology development (PE 0603115) funding.

For the Army Medical Command, this PE funds the military HIV research program to refine identification methods for determining genetic diversity of the virus, to conduct preclinical work in laboratory animals including non-human primates to identify candidates for global HIV-1 vaccine, and to evaluate and prepare overseas sites for clinical trials with these vaccine candidates.

For the Army Medical Command, funding is provided to develop strategies to prevent, mitigate, and treat antibiotic resistant bacteria in wounds through the Combating Antibiotic Resistant Bacteria - WRAIR Discovery and Wound Program.

In FY 2016, Congressional Special Interest funds were provided for Traumatic Brain Injury and Psychological Health (TBI/PH) and Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	58.251	57.275	63.550	-	63.550
Current President's Budget	64.974	57.275	63.550	-	63.550
Total Adjustments	6.723	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	11.071	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-4.348	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 200A: *Congressional Special Interests*		

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0602115DHA *I Applied Biomedical Technology*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Congressional Add: *426A – CSI - Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)*	0.000	-
Congressional Add: *462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)*	10.000	-
Congressional Add: *469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army)*	1.071	-
Congressional Add: *469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force)*	0.000	-
Congressional Add Subtotals for Project: 200A	11.071	-
Congressional Add Totals for all Projects	11.071	-

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115-Applied Biomedical Technology (-$4.179 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$4.179 million).

FY 2015: Restore core research funding to the DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$25.303 million).

FY 2016: Restore core research funding to the DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$16.904 million).

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115-Applied Biomedical Technology (-$4.114 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$4.114 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0602115-Applied Biomedical Technology (-$8.797 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+$8.797 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0602115-Applied Biomedical Technology (-$3.350 million) to DHP RDT&E PE-0603115-Medical Technology Development for Breast, Gynecological and Prostate Cancer Centers of Excellence (+$3.350 million).

FY 2017: Rebalance Joint Program Committees by realigning from DHP RDTE PE 0605145-Medical Products and Support Systems Development (-0.625M) to DHP RDTE PE 0602115-Applied Biomedical Technology (+0.625M).

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0602115DHA *I Applied Biomedical Technology*

FY 2018: No changes.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*	Project (Number/Name) 200A / *Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
200A: *Congressional Special Interests*	96.186	11.071	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

The FY 2016 DHP Congressional Special Interest (CSI) funding was directed toward core research initiatives in PE 0602115 - Applied Biomedical Technology. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 426A – CSI - Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)	0.000	-
FY 2016 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) CSI program supported studies to inform the development of strategies to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on the function, wellness, and overall quality of life for military Service members and veterans, as well as their family members, caregivers, and communities. A key priority of the TBI/PH applied research program was to complement ongoing Department of Defense efforts to ensure the health and readiness of our military forces by promoting a better standard of care for psychological health disorders and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In support, the FY 2016 Military Operational Medicine Research Program Cognitive Resilience and Readiness Research Award Program Announcement was released to solicit research relevant to building and sustaining cognitive resilience in Service members and ensuring short- and long-term readiness of the force. A Broad Agency Announcement focused on supporting the implementation of evidence-based interventions identified by stakeholders for use within the military context as well as for system-wide dissemination. Additionally, studies to identify interventions for reducing the psychological impact of stress and sex differences in the ability to predict and treat opiate abuse were initiated.		
Congressional Add: 462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)	10.000	-
FY 2016 Accomplishments: This CSI initiative was directed toward FY 2016 DHP core research initiatives in PE 0602115. Funds supported applied research for military operational medicine, combat casualty care, and radiation health effects and clinical and rehabilitative medicine (Project 372A).		
Congressional Add: 469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army)	1.071	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 200A / *Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
FY 2016 Accomplishments: FY 2016 DHP CSI was directed toward core research initiatives in PE 0602115. Funds supported research in Military HIV Research (Project 447A) and Combating Antibiotic Resistant Bacteria (Project 246A).		
Congressional Add: 469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force) ***FY 2016 Accomplishments:*** No Funding Programmed.	0.000	-
Congressional Adds Subtotals	11.071	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Individual efforts are monitored through a quarterly project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives), key performance parameters, and resolution of Force Health Protection gaps. Variances, deviations, and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of Science and Technology governance. Annual reviews are also conducted in person for all of the projects within a specific program area.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 246A / *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
246A: *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	0.000	2.913	2.860	2.142	-	2.142	1.857	1.949	1.989	2.029	Continuing	Continuing

A. Mission Description and Budget Item Justification

At the President's direction in late 2013, a National Strategy was created to address the critical issue of antimicrobial resistance. This strategy was devised using an interagency approach and ultimately approved at the executive level (2014). Inherent in this work are DoD sponsored efforts to support the DoD's beneficiaries, but also complement national efforts to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria. One critical need identified is for new therapeutics, to include antibiotics. This effort's focus is on the development of new/novel antibiotics, especially those targeting the most resistant and worrisome Gram negative bacterial pathogens, using existing expertise at the Walter Reed Army Institute of Research (WRAIR), and leveraging other WRAIR capabilities to evaluate viable candidate targets for advanced discovery. This project supports (both directly and indirectly) Global Health Security Agenda priorities to respond rapidly and effectively to biological threats of international concern.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	2.913	2.860	2.142
Description: Focus on continued establishment of in-house capabilities for an antibacterial drug discovery program directed toward military relevant drug-resistant bacteria that a) encompasses assessment of external products/candidates/leads that may meet DoD requirements, b) opens active intramural based discovery efforts of new potential products/candidates/leads for development, and c) fosters partnerships with external collaborators to develop/co-develop new potential antibacterial treatment therapeutics.			
FY 2016 Accomplishments: Established collaborations with two universities and the National Center for Advancement of Translational Science (NCATS) at the National Institutes of Health, and additional industry collaborations were initiated. In conjunction with NCATS, WRAIR identified promising drug combinations to be further assessed. Robust internal screening efforts also yielded promising early lead candidates. Efforts focused on lead optimization by specific drug design and chemical synthesis, and novel compounds were identified in two known classes of antibiotics. New animal model and bacteria susceptibility panels were established using clinically relevant pathogens derived from military populations -- these are unique tools critical for the DoD antibacterial drug discovery effort.			
FY 2017 Plans:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 246A / *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Assess identified drug combinations in WRAIR animal models; if effective, the combinations could represent potential fast-track opportunities for clinical use. Continue to optimize lead candidates, synthesize newly designed, key chemical compounds for drug lead optimization, refine animal model standards, and pursue late stage external collaborations that could potentially treat military-relevant resistant bacteria. Establish partnership and intellectual property rights agreements where necessary to explore and co-develop new antibiotics leads. ***FY 2018 Plans:*** Plans to include establishing sustainable research efforts designed to evaluate viable small molecule candidate antibacterial agents for planned development for the DoD and Public Health benefit, continuing market analysis of external antibiotic programs, compound lead optimization, and Investigational New Drug-enabling study coordination, and establishing partnership and intellectual property rights agreements where necessary to explore and co-develop new antibiotics leads. In addition,screening against military relevant strains and biofilms (microorganisms in which cells stick to each other on a surface) to select compounds for continued development will be conducted. Specially, plans made to synthesize designed novel drugs for lead optimization efforts, exploit established in vivo (living organism) model standards, and to continue to evaluate late stage external programs that could potentially treat military relevant resistant bacteria.			
Accomplishments/Planned Programs Subtotals	2.913	2.860	2.142

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

An Acquisition Strategy will be developed to support future Milestone B when a clinical development candidate is identified and reaches Technology Readiness Level (TRL)-6.

E. Performance Metrics

Performance metrics of the CARB drug discovery program will be provided through semi-annual status reports, periodic reviews by the Military Infectious Diseases Research Program Integrating Integrated Product Team (IIPT) and in-process reviews (IPR). The performance metric benchmark is progression of research projects to TRL 5 and their schedule to transition.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*	Project (Number/Name) 306B / *Advanced Diagnostics & Therapeutics Research & Development (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
306B: *Advanced Diagnostics & Therapeutics Research & Development (AF)*	9.620	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Advanced Diagnostics & Therapeutics Clinical Translational Applied Research (Air Force): This project provides applied research funding needed to increase efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Modernization Thrust Areas to improve and enhance clinical Diagnosis, Identification, Quantification and Mitigation (DIQM) methods, techniques protocols, guidelines and practices for all DoD wounded, ill and/or injured beneficiaries.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Advanced Diagnostics & Therapeutics Research & Development (AF) ***Description:*** This project provides applied research funding needed to perform research in the area of diagnostic assay development/refinement for diseases of operational significance. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and support research of evidence based therapeutics. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Plans:*** No Funding Programmed.	0.000	0.000	0.000
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 306B / *Advanced Diagnostics & Therapeutics Research & Development (AF)*

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc).

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*	Project (Number/Name) 306C / *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
306C: *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	0.000	1.728	1.757	1.987	-	1.987	2.025	2.066	2.107	2.149	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project provides applied research funding needed to perform research in the area of assay development/refinement for diseases of operational significance/ conditions. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and research/development of evidence based therapeutics

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Adv Diagnostics & Epigenomics Applied Research (AF)	1.728	1.757	1.987

Description: This project provides applied research funding needed to perform research in the area of assay development/ refinement for diseases of operational significance/conditions. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and research/development of evidence based therapeutics.

FY 2016 Accomplishments:

In support of personalized treatment for type 2 diabetes (T2D) and cardiovascular disease, provide a predictive genetic therapeutic strategy based on pharmacogenetic therapies at the onset of diagnosis and aimed at delaying disease progression. Identify genetic markers for musculoskeletal injuries and ailments to implement preventive measures in military field training sites. Perform intramural project for the rapid identification of etiological pathogens of sepsis in support of same-day treatment-specific modalities. Leverage joint personalized medicine efforts to identify biomarkers of physiological response to opioid use. Transition smartphone-based pathogen identification system to meet Air Force requirements for personalized medicine and infectious disease characterization. Optimize molecular assays for polymerase chain reaction identification of Middle Eastern Respiratory Syndrome Coronavirus and Influenza AH7N9 to be implemented within the Center for Advanced Molecular Detection infectious disease surveillance operations. Analyze breath biomarkers as an accurate and non-invasive detection of influenza infection and as a method for prediction of the clinical course of disease. Develop Human Mesenchymal Stem Cells for Treatment of Immune System Dysregulation in Neurological Diseases. Identify biomarkers for mental illness recovery, producing a validated inpatient psychiatry psychometric and biological repository. Characterize novel early biomarkers for injury severity and the coordination of patient evacuation. Analyze genotypes phenotypes within NIH databases for Air Force precision medicine applications. Validate method of MRI measurement for volumetric quantification of traumatic brain injury. Examine genetic and epigenetic biomarkers for the prevention of cutaneous adverse drug reactions. Evaluate immune-modulators for pharmacological intervention on complement activation and coagulation. Analyze serotonin transporters and telomeres to produce an early method for PTSD risk

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 306C / *Core Adv Diagnostics & Epigenomics Applied Research (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
identification. Identify proximal drivers of inflammation to predict immune status and disease. Provide an analysis of the Chagas disease threat within high-risk military populations to determine if force health protection measures should be implemented to decrease exposure risk. Develop automated data analysis method for next generation sequencing to update AF influenza surveillance program, increase epidemiological surveillance scope and reduce per result costs. ***FY 2017 Plans:*** Continue to evaluate small, rapid, ruggedized molecular detection assays and technology. Develop and compare field-forward nucleic acid extraction/sample processing methods. Examine portable, multiplexed immunoassay arrays for multiple panels, to include toxins, viruses, bacteria and biomarkers on Personalized Bioinformatics. Expand pyrosequencing assays to include fungal pathogens to decrease the diagnostic time for determining the etiological agent of sepsis. Continue the development of pharmacogenomics-driven predictive risk profiles for improved management of complex diseases. Continue the evaluation of genetic, epigenetic and proteomic markers to improve preventive and diagnostic strategies. Continue to evaluate gene-environment interactions for tailored treatments based on individual, social, operational and environmental risk and protective factors, such as those associated with social-occupational impairment, resiliency, and psychological symptoms. ***FY 2018 Plans:*** Continue to evaluate small, rapid, ruggedized molecular detection assays and technology. Develop and compare field-forward nucleic acid extraction/sample processing methods. Examine portable, multiplexed immunoassay arrays for multiple panels, to include toxins, viruses, bacteria and biomarkers on Personalized Bioinformatics. Expand pyrosequencing assays to include fungal pathogens to decrease the diagnostic time for determining the etiological agent of sepsis. Continue the development of pharmacogenomics-driven predictive risk profiles for improved management of complex diseases. Continue the evaluation of genetic, epigenetic and proteomic markers to improve preventive and diagnostic strategies. Continue to evaluate gene-environment interactions for tailored treatments based on individual, social, operational and environmental risk and protective factors, such as those associated with social-occupational impairment, resiliency, and psychological symptoms.			
Accomplishments/Planned Programs Subtotals	1.728	1.757	1.987

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 306C / *Core Adv Diagnostics & Epigenomics Applied Research (AF)*

are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 306D / *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
306D: *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	0.000	1.728	1.758	1.988	-	1.988	2.026	2.066	2.108	2.150	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project supplies applied research funding needed to further develop approaches aimed at increasing the understanding of AF occupational and environmental hazards, advancing new concepts in developing methods of treatment in aeromedical care, and exploring new mechanisms to enhance human performance in critical Air Force occupations in the defined Modernization Thrust Areas to improve and enhance, maintain, preserve, and restore personnel performance, with the end goal of positively affecting personalized health and performance.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)	1.728	1.758	1.988

Description: This project supplies applied research funding needed to further develop approaches aimed at increasing the understanding of AF occupational and environmental hazards, advancing new concepts in developing methods of treatment in aeromedical care, and exploring new mechanisms to enhance human performance in critical Air Force occupations in the defined Modernization Thrust Areas to improve and enhance, maintain, preserve, and restore personnel performance, with the end goal of positively affecting personalized health and performance.

FY 2016 Accomplishments:

Begin to develop advanced diagnostics for brain effects from hypobaria in USAF high altitude ops. Develop mitigation approaches and therapeutics to counter effects from air transport and low-dose hypobaric exposures to the brain and traumatized organ systems. Developed passive dosimeters to support 24/7 exposure monitoring. Expanded toxicological/functional testing of organ cell lines, development of new organ system cell lines and build library of multiple chemical exposure. Continued to develop environmental biosurveillance procedures for monitoring metagenomic drift within field hospitals and forward bases.

FY 2017 Plans:

Demonstrate through emerging advanced methods, brain injury from hyperoxemia/oxidant stress experienced in aircrew operations. Initial development of platforms linking biological characteristics to effects from individual and multiple environmental hazards for Total Exposure Health Initiative. Explore capture of assorted biological signatures to characterize health and physiological status.

FY 2018 Plans:

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 306D / *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Increase development of platforms linking biological characteristics to effects from individual and multiple environmental hazards for Total Exposure Health Initiative. Explore capture of assorted biological signatures to characterize health and physiological status. Proposed expansion of Genomic Studies to include analysis of conditions with operational and clinical importance, based on an assessment of AFMS needs. Continue AFMS Personalized Medicine initiatives including demonstration projects for leadings practices, evaluation and capitalization of emergent science and technologies. Utilization of patient modeling algorithms to identify pharmacogenomic interventions that can improve patient health and reduce healthcare costs across the AFMS.			
Accomplishments/Planned Programs Subtotals	1.728	1.758	1.988

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.***

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*	Project (Number/Name) 372A / *GDF Applied Biomedical Technology*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
372A: *GDF Applied Biomedical Technology*	125.005	40.072	43.462	49.639	-	49.639	58.724	67.148	68.357	69.724	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Applied Biomedical Technology: Applied biomedical technology research will focus on refining concepts and ideas into potential solutions for military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development. Applied research is managed by the Joint Program Committees in the following areas: 1- Medical Simulation and Information Sciences applied research is developing informatics-based simulated military medical training. 2- Military Infectious Diseases applied research is developing protection and treatment products for military relevant infectious diseases. 3- Military Operational Medicine applied research goals are to develop medical countermeasures against operational stressors, prevent musculoskeletal, neurosensory, and psychological injuries during training and operations, and to maximize health, performance and fitness of Service members. 4- Combat Casualty Care applied research is focused on optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through en route and facility care. 5- Radiation Health Effects applied research supports tasks for the development of radiation medical countermeasures. 6- Clinical and Rehabilitative Medicine applied research is focused on efforts to reconstruct, rehabilitate, and provide care for injured Service members.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: GDF Applied Biomedical Technology	40.072	43.462	49.639
Description: Applied Biomedical Technology Research focuses on refining concepts and ideas into potential solutions to military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development.			
FY 2016 Accomplishments: Military infectious diseases research supported multi-year studies in bacterial diseases, and continued the development efforts of four antibacterial projects and two projects for the detection of microbial infections in wounds. Studies were aimed at development of novel therapeutics (drugs), biomarkers, and clinical practice guidelines to mitigate wound infection and biofilm processes. Molecule(s) showing efficacy in laboratory studies and initial animal studies, and/or biomarkers demonstrating accuracy in identifying pathogens were evaluated for further development. Continued efforts to maintain subject matter expertise in acute respiratory diseases. These studies aligned with the National Strategy for Combating Antibiotic Resistance. Military operational medicine research validated repeated low level blast injury animal models compared to occupational blast exposures. Developed computational models of the nonlinear middle ear function to establish hearing injury criteria. Developed improved clinical strategies to determine safe return to duty after severe musculoskeletal injury, and characterized the effects of hypoxia (oxygen deficiency) and fatigue on aircrew performance in rotary and fixed wing aircraft. Conducted applied research to develop strategies for building Service member and family resilience and to support successful reintegration following deployment.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Continued to establish associations between military service, deployment, risk and protective factors, and psychological and physiological health problems to inform development of policies and guidelines. Continued research toward investigation of risk and protective factors associated with PTSD, the neurobiological and behavioral impact of various PTSD interventions, and the initiation of pilot research associated with novel, theoretically-based treatments. Developed interventions for sustainable weight loss in military families. Continued the development of computational models that can predict bone and muscle health status. Performed studies of risk factors for heat injury susceptibility and developed a non-invasive tool for diagnosing pulmonary disease. Conducted studies for novel mitigation and treatment strategies and biomarker detection to optimize physiological performance and protect against multi-environmental injury. Refined biomarkers of environmental exposure to toxic substances inhaled or ingested that will be used for establishing the probability of adverse health risk outcomes. Conducted studies to define metrics for optimized performance in extreme environmental conditions. Combat casualty care hemorrhage research continued to search for new diagnostic tools and the development of treatments for abnormal hemorrhage following injury. Work focused primarily on inflammatory modulation and coagulopathy of trauma. Forward Surgical and Intensive Critical Care studied the effectiveness of acute lifesaving surgical interventions and how to improve survival for those in need of critical care on the battlefield and in acute stages of injury. Treatments for tissue injury related to burn, acute lung injury, and enhanced healing of complex injuries of the face, extremities, groin and pelvis were studied. Tissue injury research addressed wound stabilization in the prolonged field care scenario and continued to specifically address the need for a maxillofacial stabilization dressing. En Route Care research studied the physiologic response to transport in air, sea, and ground environments and the appropriate time(s) to transport patients following injury. Radiation health effects research continued strategies for protection, mitigation, and treatment of radiation-induced tissue injury due to high doses of radiation exposure. Conducted animal studies in mice and non-human primates to evaluate several compounds with potential to mitigate or prevent Acute Radiation Syndrome (ARS) resulting from lethal doses of radiation. Mitigators and therapeutics of ARS addressed bone marrow (hematopoietic) and gastrointestinal effects. Pulmonary effects of radiation exposure were examined. Based on research accomplishments, compounds were evaluated as potential candidates for transition toward advanced development. Additional efforts evaluated targets for safe and effective candidate medical countermeasures for the mitigation or treatment of radiation injury, and increasing understanding of the molecular mechanisms by which radiation injuries are initiated and cell cycling pathways triggered leading to multi-organ system dysfunction and death. Clinical and rehabilitative medicine research pursued down-selection of candidate products for transition to technology development in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and sensory (hearing, sight, and balance) system traumatic injury. Conducted applied research in Service-related neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment, and rehabilitation. Studied the effectiveness of leading solutions to alleviate acute and chronic battlefield pain. Investigated solutions to replace or regenerate human cells, tissues, or organs to			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
restore or establish normal tissue function. Conducted applied research to identify therapeutic targets to restore visual, auditory, and vestibular function following traumatic injury. ***FY 2017 Plans:*** Military infectious diseases research continues to support multi-year studies in bacterial diseases research, and down-selecting promising efforts for further development. Releasing program announcements in wound infection to address critical research focus areas such as the ability to predict infection and better treatment options for infections with multi-drug resistant organisms (MDROs), and developing biomarker assays. Continuing efforts to maintain subject matter expertise in acute respiratory diseases. These efforts support the National Strategy for Combating Antibiotic Resistance. Military operational medicine research is collecting experimental data to validate whole-body computational models for the direct and indirect mechanism of blast brain injury and quantifying the biomechanical brain-tissue response. Determining optimal temporal spacing of repeated blast events to prevent cumulative effects. Collecting impulse noise experimental data to validate computational models of the inner ear to validate injury criteria. Developing comprehensive aircrew performance risk models of fatigue and hypoxia (oxygen deficiency). Monitoring the patterns of dietary supplement use in the Armed Forces and determining demographic and lifestyle factors associated with dietary supplement and caffeine use along with coincident motivating factors. Assessing the psychosocial and physiological factors affecting overuse injury susceptibility and career success of female Warriors. Conducting applied research to develop prevention skills training and interventions to prevent suicide behaviors. Completing studies that will inform opioid abuse risk reduction strategies. Delivering prototypes for Service member and family resilience building interventions. Investigating novel and evidence-based PTSD intervention adaptations (group, couples, web-based, etc.), selecting candidate biomarkers associated with treatment, and animal/human disease model development. Refining candidate biomarkers for exposure to inhaled or ingested toxic substances for establishing the probability of adverse health risk outcomes and continue refinement of a non-invasive tool for diagnosing pulmonary disease. Conducting research to refine metrics for optimized operational task performance in extreme environmental conditions. Combat casualty care hemorrhage research is investigating new diagnostic tools and continuing the development of treatments for severe hemorrhage following injury. Work focuses primarily on modulating inflammation and coagulopathy of trauma. Research is focusing on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Inflammatory modulation (controlling the body's response to harmful stimuli) and other research is focusing on the time period from 4 to 72 hours post-injury (related to prolonged field care scenarios). Treatments for extremity trauma and advanced wound stabilization are continuing. Treatments for prolonged field care scenarios that may enhance initial treatment and improve long term outcomes for burn, acute lung injury, and complex injuries to include maxillofacial injury are continuing.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Forward Surgical and Intensive Critical Care is studying the effectiveness of acute lifesaving interventions, how to improve survival for those in need of critical care on the battlefield and in acute stages of injury and during prolonged timeframes until reaching definitive care in the pre-hospital/hospital setting. En Route Care research is studying clinically-relevant testing standards for monitors in the transport environment and is developing new non-invasive monitoring technologies. Radiation health effects research is conducting non-clinical research to identify therapeutic candidates for acute radiation exposure and developing data to support preparation of technical data package requirements for investigational new drug applications. Research is focusing on evaluating candidate radioprotectants (prophylaxes that protect against cell damage caused by radiation) to determine their feasibility and practicality as candidate solutions to military needs. Clinical and rehabilitative medicine research is selecting the most promising candidate products to transition to technology development in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and sensory system injury. Supporting applied research in neuromusculoskeletal injuries to advance the diagnosis, treatment and rehabilitation outcomes after Service-related injuries. Identifying targets for therapies to alleviate acute, chronic, and battlefield pain and identifying strategies for addressing psychosocial aspects of pain management and pain-related substance abuse. Studying pain biomarkers to implement precision medicine approaches for pain management. Evaluating candidate reconstructive and regenerative technologies to replace or regenerate human cells, tissues, or organs to restore or establish normal tissue form and function of bone, skin, muscle, nerve, vasculature and connective tissue. Investigating the neuro-biology of tinnitus and hidden noise injury. ***FY 2018 Plans:*** Medical simulation and information sciences applied research will focus on researching pharmacodynamics and pharmacokinetics algorithms to support a repository that contains simulated pharmaceuticals and other resuscitative treatments that are the most relevant to point of injury and en route care training. The mathematical algorithms will focus on specific pharmacodynamics and pharmacokinetics as well as absorption, distribution, metabolism, and excretion of the pharmaceuticals and resuscitative options. Will support research on high fidelity tactile haptics (recreated sense of touch in simulated settings) to improve tactile sensation and resistance realism of virtual reality systems and mannequin based medical training systems. Military infectious diseases research will support previously initiated multi-year studies in bacterial diseases research, and will down-select promising efforts for further development. Multi-year studies initiated in FY17 through program announcements in wound infection will be supported to address critical research focus areas such as the ability to predict infection and better treatment options for infections with MDROs and development of biomarker assays for diagnosis of infection. Will develop novel and innovative therapeutics and delivery technologies for combat wound infections. Will maintain subject matter expertise in acute respiratory diseases. These efforts will support the National Strategy for Combating Antibiotic Resistance. Will maintain scientific			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
awareness and a capability to respond to emerging infectious diseases. Will partner with other entities to rapidly accelerate promising, innovative drug and vaccine solutions to combat emerging infectious diseases (e.g., Chikungunya, MERS, Zika). Military operational medicine research will continue to collect experimental data to validate whole-body computational models of the direct and indirect mechanism of blast brain injury. Will determine optimal temporal spacing of repeated blast events to prevent cumulative effects and analyze changes in brain injury biomarkers. Will collect impulse noise experimental data from volunteer subjects to validate computational models of inner ear injury. Will continue to refine comprehensive aircrew performance risk models of fatigue and hypoxia (oxygen deficiency). Will refine models of dietary supplement use patterns by Armed Forces members and determine demographic and lifestyle factors associated with dietary supplement and caffeine use along with risks and benefits of consumption. Will continue to assess the physical, psychosocial and physiological factors affecting overuse injury susceptibility and career success of female Warriors. Will continue to deliver prototypes for Service member and family resilience building interventions. Will begin studies aimed at delivering an evidence-based substance abuse prevention and training model and screening and compliance tools. Will begin to conduct research to deliver an evidence-based approach to reduce stigma and a training program to increase provider skill in assessing and treating suicidality. Will continue to investigate novel and evidence-based PTSD interventions. Will investigate adaptations in delivery of care toward the goal of increased accessibility. Will identify and develop candidate biomarker panels indicative of treatment-related improvement, and animal/human PTSD disease model development. Will analyze novel compounds and existing FDA-approved medications for potential use in treatment of PTSD. Will continue to refine candidate biomarkers of exposure to inhaled or ingested toxic substances for establishing the probability of adverse health risk outcomes, and continue refinement of a non-invasive tool for diagnosing pulmonary disease. Will continue to conduct research to refine metrics for optimized operational task performance in extreme environmental conditions. Combat casualty care hemorrhage research will investigate new diagnostic tools and will continue the development of treatments for severe hemorrhage following injury. Will continue to focus on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Will initiate studies of novel oxygen carriers for use in severe casualties where blood transfusions are not available. Inflammatory modulation and other research will continue its focus on the time period from 4 to 72 hours post-injury (related to prolonged field care scenarios). Tactical Combat Casualty Care (TCCC) will investigate novel approaches to enable field care of casualties when evacuation is delayed. Neurotrauma research will focus on precision medicine capabilities. This research will improve the characterization of TBI, lead to the development of targeted therapies, devices and clinical guidelines to improve the care provided to TBI casualties, investigate the impact of pre-injury conditions, genomics (study of genes in an organism), proteomics (study of all the proteins in a cell) and the environment on Service member response to treatment and recovery following TBI. This will lead to an understanding of the factors that influence and inform patient responsiveness to TBI therapeutic interventions, as well as the role of environmental and physiological factors that impact injury outcomes. Treatments for extremity trauma will continue to advance wound stabilization for prolonged field care scenarios that might enhance initial treatment and improve longer term outcomes.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Development of closed loop and decision assist technologies for burns, lung ventilation, organ support, and other complex injuries to include maxillofacial injury will continue. Pre-hospital Tactical Combat Casualty Care area will study the effectiveness of acute lifesaving interventions and how to improve survival for those in need of critical care on the battlefield, in acute stages of injury, and for those requiring prolonged times until reaching definitive care in the prolonged field care/pre-hospital/hospital setting. En Route Care research will continue to study clinically-relevant testing standards for monitors in the transport environment and develop new non-invasive monitoring technologies. Radiation health effects research will continue to conduct non-clinical research to identify therapeutic candidates for acute radiation exposure and develop data to support preparation of technical data package requirements for investigational new drug applications. Research will also focus on evaluating candidate preventative radioprotectants to determine their feasibility and practicality as candidate solutions to military needs. Objectives will include identifying mechanisms of action, efficacy and safety data in animal models for medical countermeasures for ARS. Clinical and rehabilitative medicine research will select the most promising candidate products to transition to technology development in the areas of neuromusculoskeletal injury, pain management, and regenerative medicine. Will support applied research in neuromusculoskeletal injuries to advance the diagnosis, treatment and rehabilitation outcomes after Service-related injuries. Will identify targets for therapies to alleviate acute, chronic, and battlefield pain and identify strategies for addressing psychosocial aspects of pain management and pain-related substance abuse. Will study pain biomarkers to implement precision medicine approaches for pain management. Will develop candidate reconstructive and regenerative technologies and methodologies for replacement or regeneration of human cells, tissues, or organs for restoration or establishment of normal tissue form and function of bone, skin, muscle, nerve, vasculature and connective tissue.			
Accomplishments/Planned Programs Subtotals	40.072	43.462	49.639

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Evaluate technical feasibility of potential solutions to military health issues. Implement models into data or knowledge and test in a laboratory environment. Technology Transition and Milestone A packages will be developed to facilitate product transition.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, quarterly and annual status reports to include information on publications, intellectual property, additional funding support, and progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. The benchmark performance metric for transition of research conducted with applied research funding is the attainment of a maturity level that is at least Technology Readiness Level (TRL) 4, and typically TRL 5, or the equivalent for knowledge products. Products nearing attainment of TRL 5 will be considered for transition.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*	Project (Number/Name) 447A / *Military HIV Research Program (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
447A: *Military HIV Research Program (Army)*	14.959	7.462	7.438	7.794	-	7.794	9.022	9.654	9.847	10.044	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project conducts research on the human immunodeficiency virus (HIV), which causes acquired immunodeficiency syndrome (AIDS). This effort supports the Administration's priorities in the area of international scientific partnership in global health engagement. Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for clinical trials with global vaccine candidates. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals. This project is jointly managed through an Interagency Agreement between U.S. Army Medical Research and Materiel Command (USAMRMC) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health. This project contains no duplication of effort within the Military Departments or other government organizations. The cited work is also consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas, and supports the principal area of Military Relevant Infectious Diseases to include HIV.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Military HIV Research Program	7.462	7.438	7.794
Description: This project conducts research on HIV, which causes AIDS. Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for future vaccine trials. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals.			
FY 2016 Accomplishments: FY16 accomplishments includes producing additional vaccine candidates for various world-wide subtypes and characterized these new sub-types and evaluated their capability to induce protective immune responses in non-human primates. In addition, one or more vaccine candidates were down-selected for use in safety studies in human volunteers.			
FY 2017 Plans: FY17 Plans include finalizing production and optimization of three new vaccine candidates from an East African region, characterizing these new sub-types and evaluating their capability to induce protective immune responses in non-human primates by using novel delivery systems, and down-selecting one vaccine candidate from an East African region for use in a human clinical trial to test for safety and immunogenicity (ability to invoke an immune response). In addition, an optimal delivery system containing a diverse mixture of antigens (substance that induces an immune response) for HIV subtypes A, C, D and E and test in non-human primates will be designed. This program continues to develop new clinical trial sites in Mozambique that will allow			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 447A / *Military HIV Research Program (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
scientists the opportunity to test future vaccine candidates against the predominant HIV subtype (C) circulating in this part of the world. ***FY 2018 Plans:*** In Fy18, plans are to develop and optimize methods of large scale production of new vaccine candidates for testing in Africa and Asia representing the breadth of HIV diversity. This program will produce and characterize these new vaccine candidates for use in pre-clinical and clinical testing as well as evaluate the vaccine candidates of interest to assess their capability to induce protective immune responses in non-human primates by using novel delivery systems. It will continue to down-select one or more vaccine candidates from non-human primate studies to test for safety and immunogenicity(ability to invoke an immune response) and optimize a delivery system containing a diverse mixture of antigens (substance that induces an immune response) for HIV subtypes A, B, C, D and E and test in non-human primates. New clinical trial sites will be identified and developed in Europe, Southeast Africa Asia and the US that will allow scientists the opportunity to test future vaccine candidates against predominant HIV subtypes circulating in this part of the world.			
Accomplishments/Planned Programs Subtotals	7.462	7.438	7.794

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

The program receives periodic funding from Division of AIDS of NIAID ranging from $10-20 million per year through an Interagency Agreement with USAMRMC.

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance of the HIV research program is monitored and evaluated through an external peer review process, with periodic reviews by the HIV Program Steering Committee and the Military Infectious Diseases Research Program Integrating Integrated Product Team and in-process reviews.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0602787DHA *I Medical Technology (AFRRI)*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	7.002	1.131	1.242	1.331	-	1.331	1.356	1.383	1.411	1.439	Continuing	Continuing
020: *CSI - Congressional Special Interests*	0.124	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
241A: *Biodosimetry (USUHS)*	1.403	0.231	0.254	0.272	-	0.272	0.277	0.283	0.289	0.295	Continuing	Continuing
241B: *Internal Contamination (USUHS)*	0.730	0.121	0.133	0.143	-	0.143	0.146	0.149	0.152	0.155	Continuing	Continuing
241C: *Radiation Countermeasures (USUHS)*	4.745	0.779	0.855	0.916	-	0.916	0.933	0.951	0.970	0.989	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USUHS), Armed Forces Radiobiology Research Institute (AFRRI), this program supports developmental research to investigate new approaches that will lead to advancements in biomedical strategies for preventing, treating, assessing and predicting the health effects of human exposure to ionizing radiation. Program objectives focus on preventing or mitigating the health consequences from exposures to ionizing radiation that represent the highest probable threat to U.S. forces in current tactical, humanitarian and counterterrorism mission environments. New protective and therapeutic strategies will broaden the military commander's options for operating within nuclear or radiological environments by minimizing both short-and long-term risks of adverse health consequences. Advances in assessment, prognostication, and therapy in case of actual or suspected radiation exposures will enhance triage, treatment decisions and risk assessment in operational settings.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	1.222	1.242	1.331	-	1.331
Current President's Budget	1.131	1.242	1.331	-	1.331
Total Adjustments	-0.091	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.091	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 020: *CSI - Congressional Special Interests*		
Congressional Add: *472A – Program Increase: Restore Core Research Funding Reduction (USUHS)*	0.000	-

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0602787DHA *I Medical Technology (AFRRI)*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Congressional Add Subtotals for Project: 020	0.000	-
Congressional Add Totals for all Projects	0.000	-

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0602787-Medical Technology (AFRRI) (-$0.091 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$0.091 million).

FY 2017: No Change.

FY 2018: No Change.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / *Medical Technology (AFRRI)*	Project (Number/Name) 020 / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
020: *CSI - Congressional Special Interests*	0.124	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY15 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0602787 - Medical Technology (AFRRI). Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 472A – Program Increase: Restore Core Research Funding Reduction (USUHS) ***FY 2016 Accomplishments:*** No Funding Programmed.	0.000	-
Congressional Adds Subtotals	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / *Medical Technology (AFRRI)*	Project (Number/Name) 241A / *Biodosimetry (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
241A: *Biodosimetry (USUHS)*	1.403	0.231	0.254	0.272	-	0.272	0.277	0.283	0.289	0.295	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USU), Armed Forces Radiobiology Research Institute (AFRRI), this program supports developmental research to investigate new approaches that will lead to advancements in biomedical strategies for preventing, treating, assessing and predicting the health effects of human exposure to ionizing radiation. Program objectives focus on preventing or mitigating the health consequences from exposures to ionizing radiation that represent the highest probable threat to U.S. forces in current tactical, humanitarian and counterterrorism mission environments. New protective and therapeutic strategies will broaden the military commander's options for operating within nuclear or radiological environments by minimizing both short-and long-term risks of adverse health consequences. Advances in assessment, prognostication, and therapy in case of actual or suspected radiation exposures will enhance triage, treatment decisions and risk assessment in operational settings.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Biodosimetry (USUHS)	0.231	0.254	0.272
Description: For the Uniformed Services University of the Health Sciences (USU), the mission and research objectives for biodosimetry are to assess radiation exposure by developing and providing biological and biophysical dosimetry capabilities for acute, protracted, and prior radiation exposures for all relevant military applications.			
FY 2016 Accomplishments: Sustained studies evaluating radiation-responsive biomarkers in animal models for early-phase and organ-specific bioindicators. Provided necessary proof-of-concept dose-response data to transition combined proteomic and hematological concept for further development of diagnostic devices (i.e., hand-held, field deployable). Reported on hematology and blood serum chemistry data collected in NHP radiation study with limited- and full-supportive care (G-CSF, antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs. Continued efforts to establish robust cytogenetic biodosimetry capability; initiated studies to characterize length ratio (ratio of longest to smallest chromosome) using premature chromosome condensation assay in irradiated lymphocytes. Evaluated diagnostic utility of urinary radiation biomarkers using radiation doses (0 Gy, 1 Gy, 3.5 Gy, 5.0 Gy, 6.5 Gy and 8.5 Gy) in nonhuman primate model between 1-30 days post-irradiation; Completed analysis of urinary amylase and CRP where results were not correlated with radiation dose; Measured changes in urine IL-18 expression up to 5 days post-irradiation, showing diagnostic usefulness for distinguishing radiation exposure. Evaluated 5 of total 18 proposed new radiation-responsive protein biomarkers in mouse and nonhuman primate (NHP) total-body irradiation (TBI) models for early-phase and organ-specific damage. Plasma citrullinated proteins were evaluated as potential new biomarkers of epithelial radiation-induced small bowel damage in animal models using commercially available antibodies and assays developed at AFRRI by Dr. Ossetrova (Ossetrova NI. “Immunoassays for Citrullinated Proteins”, PCT/US2009/061660, filed on October 22, 2009, claiming priority to U.S. Provisional Application No. 61/107,446, filed on October 22, 2008. US Patent Number 9,063,148 issued on 6/23/2015).			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241A / *Biodosimetry (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Citrullinated proteins evaluated as new predictive radiation-responsive biomarkers in animal model acute radiation sickness (ARS). Completed analyses of hematology and blood serum chemistry collected in NHP dose-response study with limited and full supportive care (i.e., G-CSF or Neupogen® [filgrastim], antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs. Completed analyses of necropsies performed on NHPs in studies with limited and full supportive care (i.e., G-CSF or Neupogen® [filgrastim], antibiotics, blood transfusions, etc.) to determine radiation dose-dependent damage to different organs/tissues and correlate those results with levels of already evaluated tissue/organ-specific protein biomarkers. Some results/data from NHP dose-response TBI (photon/low LET) studies were compared with results collected from radiation accident victims and radiation therapy patients, which revealed very good similarities. Reported on development of IL-18 and IL-18 binding protein (IL-18BP) as dual biomarkers for assessment of radiation dose, severity and lethality in mice after TBI. Reported microRNA-30, as a radiation biomarker, inhibits antiapoptotic factor Mcl-1 and induces apoptosis in mouse and human hematopoietic cells after radiation exposure. Identified two hematology and leukemia markers during leukemogenesis that were differentially expressed at early and late phases of transformation. Determined that epigenetic changes, i.e., histone acetylation markers, could discriminate between differences in dose rate at low doses (<10 cGy).			
FY 2017 Plans: Perform partial-body radiation exposure study to characterize organ specific injury biomarkers using abdomen exposures of mice. Initiate studies to evaluate radiation-induced chromosomal damage in murine radiation model. Develop multivariate discriminate model using several endpoints measured in premature chromosome condensation assay to assess radiation dose. Establish partial-body radiation model using mice involving exposure of abdomen with AFRRI's small animal irradiator to support studies identifying and validating organ (i.e., small intestine, kidney) injury biomarkers. Initiate use of commercially available automated dicentric scoring software to generate dose-response for dicentric yields in irradiated lymphocytes. Participate in annual performance evaluations to demonstrate accuracy in dose assessment by cytogenetics. Evaluate correlations between levels of radiation biomarkers (IL-18, IL-18BP and miR-34) and survival rate in individual mice 1 to 40 days after radiation. Evaluate effects and mechanisms of proinflammatory cytokine IL-18 and IL-18BP in radiation-induced cell damage and apoptosis pathways. Develop circulating miRNA profile in serum from mice exposed to different doses of gamma-radiation mouse serum using miRNA microarray and quantitative reverse transcription (RT)-real-time-polymerase chain reaction (PCR). Study signal pathways regulated by miRNAs in response to different radiation doses. Continue with further analysis of natural history of diagnostic usefulness of urine IL-18 with remaining samples using archived nonhuman primate samples. Apply IL-18 biomarker in combination with blood biomarkers in multivariate regression analysis approach for estimating degree of radiation injury/exposure. Continue evaluating new predictive radiation-responsive biomarkers in animal models for prediction of ARS severity and outcome. Continue studies to evaluate new radiation-responsive biomarkers in animal models for early-phase and organ-specific damage. Continue correlating other early-phase and organ-specific damage biomarkers with results of necropsies performed on NHPs in studies with limited and full supportive care (i.e., G-CSF or Neupogen® [filgrastim], antibiotics, blood transfusions, etc.) to determine radiation dose-dependent damage to different organs/tissues. Continue comparing results/data from NHP dose-			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241A / *Biodosimetry (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
response TBI (photon/low LET) studies with data collected from radiation accident victims and radiation therapy patients. Continue evaluating new predicative radiation-responsive biomarkers in animal models for a prediction of the ARS severity and outcome. Evaluate additional hematology and leukemia markers during leukemogenesis that are differentially expressed at early and late phases of transformation. Identify additional epigenetic changes that discriminate between differences in dose rate at low doses (<10 cGy). ***FY 2018 Plans:*** Establish suite of biodosimetry analysis software tools and standard operating procedures to support analysis of chromosomal aberrations used in radiation dose assessment. Establish dose-response for dicentric yields in irradiated lymphocytes using automated dicentric scoring software utility. Perform dose response study measuring dicentric chromosomal aberrations after exposure to mixed neutron and photon radiation. Identify radiation-responsive targets (i.e., miRNA, proteomic) specific to radiation sensitive organ systems in mouse partial-body exposure model. Participate in annual performance evaluations to demonstrate accuracy in dose assessment by cytogenetics; implement processes to enhance throughput capability for processing and scoring of chromosomal aberrations. Establish partial-body animal radiation models (mouse) using low-LET/photon exposure with AFRRI small-animal irradiator (for mice) to assess organ-specific radiation injury biomarkers evaluated earlier in low-LET TBI studies. Establish partial-body animal radiation models (mouse and NHP) using low-LET/photon exposure with AFRRI small-animal irradiator (for mice) and LINAC (for NHPs) to assess organ-specific radiation injury biomarkers evaluated earlier in low-LET TBI studies. Establish mouse TBI model for combined hematological and proteomic biodosimetry approach following mixed-field (neutrons and photons, high-LET) in addition to one already established and evaluated for a pure photon (60Co gamma-rays, low-LET) exposure. Develop IL-18 and IL-12 as dual radiation biomarkers in non-human primate urine for assessment of radiation doses, severity and lethality after TBI. Develop miRNA profile in urine of gamma-irradiated NHPs using miRNA microarray and quantitative RT-PCR. Compare miRNA profiles in gamma-irradiated mouse serum and NHP urine and identify sensitive and accurate radiation biomarkers. Evaluate effects of low and moderate doses of gamma-radiation on hematopoietic and immune system of mice (in vivo) and human cells (in vitro). Evaluate mechanisms of radiation-induced lymphocyte damage. Evaluate additional hematology and leukemia markers during leukemogenesis that are differentially expressed at early and late phases of transformation. Identify additional epigenetic changes that discriminate between differences in dose rate at low doses (<10 cGy).			
Accomplishments/Planned Programs Subtotals	0.231	0.254	0.272

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241A / *Biodosimetry (USUHS)*

E. Performance Metrics

By FY 2016
- Demonstrate accuracy in dose assessment by cytogenetics chromosomal aberration assay in blind exercise.
- Report on efforts to provide algorithms to convert radiation-responsive biomarkers data to radiation dose and injury.
- Complete analysis of archived AFRRI NHP urine samples (1-30 days post-irradiation) for variations in NHP urine metabolite levels, amylase and C-reactive protein, and IL-18 associated with different radiation doses (0 Gy, 1 Gy, 3.5 Gy, 5.0 Gy, 6.5 Gy and 8.5 Gy (in collaboration with NIH using tandem mass spectroscopy, WRAIR).
- Continue analyses of blood samples from mouse and NHP TBI models to identify novel tissue- and organ-specific biomarkers.
- Continue correlating other early-phase and organ-specific damage biomarkers with results of necropsies performed on NHPs in studies with limited and full supportive care (i.e., G-CSF or Neupogen® [filgrastim], antibiotics, blood transfusions, etc.) to determine radiation dose-dependent damage to different organs/tissues.
- Complete analyses of blood serum chemistry collected in NHP dose-response studies with limited and full supportive care (i.e., G-CSF or Neupogen® [filgrastim], antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs.
- Provide proof-of-concept dose-response data to transition combined proteomic and hematological concept for further development of diagnostic devices (i.e., hand-held, field deployable) in support of FDA approval.

By FY 2017
- Perform initial analysis of multiple parameter biodosimetry assessment using murine partial-body exposure model.
- Establish use of automated metaphase finder to enhance throughput for processing samples and automated scoring of dicentrics.
- Evaluate correlations between levels of radiation biomarkers (IL-18, IL-18BP and miR-34) and survival rates in individual mice 1 to 40 days after radiation.
- Report on further analysis of IL-18 and develop algorithm using IL-18 as significant variable for use in combination with archived complete blood count and serum chemistry data (from same NHP dataset) for estimating radiation injury.
- Develop biomarkers which can identify “treatment-point” in individual mice after radiation injury.
- Identify the network of miRNAs and their targeted mRNAs in radiation-induced apoptotic signal pathways.
- Continue evaluating new early-phase and organ-specific damage radiation-responsive biomarkers in animal models.
- Continue comparing and correlating hematology, blood serum chemistry, protein biomarkers and necropsy results in NHP dose-response study to evaluate radiation damage to specific organs.
- Continue comparing results/data from NHP dose-response TBI (photon/low LET) studies with data collected from radiation accident victims and radiation therapy patients.
- Continue refining combination of radiation biomarkers in blood with best balance of discrimination, sensitivity and specificity.
- Continue evaluating the predictive radiation-responsive biomarkers in animal models for prediction of ARS severity and outcome.
- Measure specific methylation and histone changes using RT-PCR in low dose and high dose exposed murine spleen samples.

By FY2018
- Characterize partial-body animal radiation models (murine) using animals involving low-LET exposure with AFRRI small-animal irradiator (for mice) to identify organ-specific radiation injury biomarkers evaluated earlier in low-LET TBI studies.
- Initiate studies to characterize cytogenetic chromosomal aberration yields following exposure to neutron and photon mixed field sources.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241A / *Biodosimetry (USUHS)*

- Perform mass-casualty exercise to test throughput capability in dose assessment by cytogenetics.
- Continue scoring dicentric aberrations following exposure to neutron and photon mixed field exposures.
- Establish partial-body animal radiation models (mouse and NHP) using low-LET photon exposure with AFRRI small-animal irradiator (for mice) and LINAC (for NHPs) to identify organ-specific radiation injury biomarkers evaluated earlier in low-LET TBI studies.
- Establish mouse TBI model for combined hematological and proteomic biodosimetry following mixed-field (neutrons and photons, high-LET) in addition to one already established and evaluated for a pure photon (60Co gamma-rays, low-LET) exposure.
- Develop miRNA profile for urine of gamma-irradiated NHPs urine using miRNA microarray and quantitative RT-PCR.
- Evaluate IL-18 and IL-12 as dual radiation biomarkers in NHP urine.
- Evaluate effects of low-moderate doses of gamma-radiation on hematopoietic and immune cell injury.
- Develop miRNA profile and identify sensitive and accurate biomarkers in mouse and human hematopoietic and immune cells after low-moderate doses radiation exposure.
- Evaluate effects of low-moderate doses of radiation on induced proinflammatory factor activation in mouse thymus, BM and spleen cells and human CD34+ cells.
- Ascertain mechanisms by which low-moderate doses of radiation induce stress responses in mouse and human immune and hematopoietic cells, and lymphocyte depletion.
- Initiate murine leukemia model to concomitantly predict leukemia development based on epigenetic markers identified in FY16 and FY17.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / *Medical Technology (AFRRI)*	Project (Number/Name) 241B / *Internal Contamination (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
241B: *Internal Contamination (USUHS)*	0.730	0.121	0.133	0.143	-	0.143	0.146	0.149	0.152	0.155	Continuing	Continuing

A. Mission Description and Budget Item Justification

Internal Contamination (USU): For the Uniformed Services University of the Health Sciences (USU), the mission and research objective for Internal Contamination is to determine whether the short-term and long-term radiological and toxicological risks of embedded metals warrant changes in the current combat and post-combat fragment removal policies for military personnel. Additionally, the biological effects of internalization of radioactive elements from Radiological Dispersal Devices (RDDs) and depleted uranium weapons, as well as therapeutic approaches to enhance the elimination of radionuclides from the body are being investigated.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Internal Contamination (USUHS)	0.121	0.133	0.143

Description: Internal Contamination (USU): For the Uniformed Services University of the Health Sciences (USU), the mission and research objective for Internal Contamination is to determine whether the short-term and long-term radiological and toxicological risks of embedded metals warrant changes in the current combat and post-combat fragment removal policies for military personnel. Additionally, the biological effects of internalization of radioactive elements from Radiological Dispersal Devices (RDDs) and depleted uranium weapons, as well as therapeutic approaches to enhance the elimination of radionuclides from the body are being investigated.

FY 2016 Accomplishments:
Began synthesis of molecularly imprinted polymers using non-radioactive templates to assess potential of using these non-hazardous surrogates to prepare compounds for decorporation of high-specific activity radionuclides. Completed assessment of surrogate-templated molecularly imprinted polymers with respect to binding specificity and initiated cytotoxicity assessments.

FY 2017 Plans:
Continue assessment of surrogate-templated molecularly imprinted polymers with respect to binding specificity. Initiate cytotoxicity assessments of newly synthesized molecularly imprinted polymers.

FY 2018 Plans:
Continue cytotoxicity testing of surrogate-templated molecularly imprinted polymers; begin assessment of extracorporeal decorporation ability in laboratory rat model. Design feasibility study to assess potential of chemically-modified dendrimeric structures as radionuclide decorporation agents. Design feasibility study to assess potential of chemically-modified dendrimeric structures as radionuclide decorporation agents. Continue assessment of dendrimeric structures as potential radionuclide

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241B / *Internal Contamination (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
decorporation agents as regards specificity, binding strength and cytotoxicity. Initiate a study to determine if non-toxic plant-based metal chelators can be effectively used as radionuclide decorporation agents.			
Accomplishments/Planned Programs Subtotals	0.121	0.133	0.143

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY 2017
- Complete molecularly imprinted polymer binding specificity studies; initiate cytotoxicity assessments.

By FY2018
- Complete cytotoxicity and extracorporeal decorporation assessments of surrogate-templated molecularly imprinted polymers.

By FY2019
- Initiate study into feasibility of chemically-modified dendrimeric structures as radionuclide decorporation agents.

By FY2020
- Complete feasibility study on the use of chemically-modified dendrimeric structures as radionuclide decorporation agents and determine if continued investigation is warranted.

By FY2021
- Initiate investigation into the applicability of non-toxic plant-based chelators as radionuclide decorporation agents using in vitro model systems.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / *Medical Technology (AFRRI)*	Project (Number/Name) 241C / *Radiation Countermeasures (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
241C: *Radiation Countermeasures (USUHS)*	4.745	0.779	0.855	0.916	-	0.916	0.933	0.951	0.970	0.989	Continuing	Continuing

A. Mission Description and Budget Item Justification

Radiation Countermeasures (USU): For the Uniformed Services University of the Health Sciences (USU), this program supports developmental, mission directed research to investigate new concepts and approaches that will lead to advancements in biomedical strategies for preventing and treating the health effects of human exposure to ionizing radiation as well as radiation combined with injuries (burns, wounds, hemorrhage), termed combined injury (CI). Research ranges from exploration of biological processes likely to form the basis of technological solutions, to initial feasibility studies of promising solutions. Program objectives focus on preventing and mitigating the health consequences from exposures to ionizing radiation, in the context of probable threats to U.S. forces in current tactical, humanitarian and counterterrorism mission environments. New protective and therapeutic strategies will broaden the military commander's options for operating within nuclear or radiological environments by minimizing both short-and long-term risks of adverse health consequences.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Radiation Countermeasures (USUHS)	0.779	0.855	0.916

Description: Radiation Countermeasures (USU): For the Uniformed Services University of the Health Sciences (USU), this program supports developmental, mission directed research to investigate new concepts and approaches that will lead to advancements in biomedical strategies for preventing and treating the health effects of human exposure to ionizing radiation as well as radiation combined with injuries (burns, wounds, hemorrhage), termed combined injury (CI). Research ranges from exploration of biological processes likely to form the basis of technological solutions, to initial feasibility studies of promising solutions. Program objectives focus on preventing and mitigating the health consequences from exposures to ionizing radiation, in the context of probable threats to U.S. forces in current tactical, humanitarian and counterterrorism mission environments. New protective and therapeutic strategies will broaden the military commander's options for operating within nuclear or radiological environments by minimizing both short-and long-term risks of adverse health consequences.

FY 2016 Accomplishments:

Sustained studies evaluating radiation-responsive biomarkers in animal models for early-phase and organ-specific bioindicators. Provided necessary proof-of-concept dose-response data to transition combined proteomic and hematological concept for further development of diagnostic devices (i.e., hand-held, field deployable). Reported on hematology and blood serum chemistry data collected in NHP radiation study with limited- and full-supportive care (G-CSF, antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs. Identified additional hematology and leukemia markers during leukemogenesis that are differentially expressed at early and late phases of transformation including miRNAs. Using two models of neutron energy spectra, measured a differential pattern in miRNA biomarkers between neutron radiation expected at close distance to epicenter and at longer distances from epicenter. Identified additional epigenetic changes that discriminate between differences in dose rate at low

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241C / *Radiation Countermeasures (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
doses (<10 cGy) and determined that acetylation was more significantly affected and may be a useful bio-indicator. Continued efforts to establish robust cytogenetic biodosimetry capability; initiated studies to characterize length ratio (ratio of longest to smallest chromosome) using premature chromosome condensation assay in irradiated lymphocytes. Evaluated diagnostic utility of urinary radiation biomarkers using radiation doses (0 Gy, 1 Gy, 3.5 Gy, 5.0 Gy, 6.5 Gy and 8.5 Gy) in nonhuman primate model between 1-30 days post-irradiation; Completed analysis of urinary amylase and CRP where results were not correlated with radiation dose; Measured changes in urine IL-18 expression up to 5 days post-irradiation, showing diagnostic usefulness for distinguishing radiation exposure. Evaluated 5 of total 18 proposed new radiation-responsive protein biomarkers in mouse and nonhuman primate (NHP) total-body irradiation (TBI) models for early-phase and organ-specific damage. Plasma Citrullinated proteins were evaluated as a potential new biomarker of the epithelial radiation-induced small bowel damage in animal models using commercially available antibodies and assays developed at AFRRI by Dr. Ossetrova (Ossetrova NI. “Immunoassays for Citrullinated Proteins”, PCT/US2009/061660, filed on October 22, 2009, claiming priority to U.S. Provisional Application No. 61/107,446, filed on October 22, 2008. US Patent Number 9,063,148 issued on 6/23/2015. Citrullinated proteins were evaluated as a new predicative radiation-responsive biomarkers in animal models for a prediction of the acute radiation sickness (ARS) outcome. Completed the analyses of hematology and blood serum chemistry data collected in the NHP dose-response study with limited and full supportive care (i.e., G-CSF or Neupogen® [filgrastim], antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs. Completed the analyses of results of necropsies performed on NHPs in studies with limited and full supportive care (i.e., G-CSF or Neupogen® [filgrastim], antibiotics, blood transfusions, etc.) to determine the radiation dose-dependent damage to different organs/tissues and correlate those results with levels of already evaluated tissue/organ-specific protein biomarkers. Some results/data from the NHP dose-response TBI (photon/low LET) studies were compared with results collected from radiation accident victims and radiation therapy patients and revealed the very good similarities. Reported on development of IL-18 and IL-18 binding protein (IL-18BP) as dual biomarkers for assessment of radiation dose, severity and lethality in mice after TBI. Reported microRNA-30, as a radiation biomarker, inhibits antiapoptotic factor Mcl-1 and induces apoptosis in mouse and human hematopoietic cells after radiation exposure. Identified two hematology and leukemia markers during leukemogenesis that were differentially expressed at early and late phases of transformation. Determined that epigenetic changes, i.e., histone acetylation markers, could discriminate between differences in dose rate at low doses (<10 cGy). Identified additional hematology and leukemia markers during leukemogenesis that are differentially expressed at early and late phases of transformation including miRNAs. Using two models of neutron energy spectra, measured a differential pattern in miRNA biomarkers between neutron radiation expected at close distance to epicenter and at longer distances from epicenter. Identified additional epigenetic changes that discriminate between differences in dose rate at low doses (<10 cGy) and determined that acetylation was more significantly affected and may be a useful bio-indicator.			
FY 2017 Plans: Screen five new drugs in mouse model for their radiation countermeasure potential (prophylactic). Continue to evaluate micro-RNA profiles in mouse serum after both radiation alone and combination with wound trauma with treatment with countermeasures.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241C / *Radiation Countermeasures (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Complete analysis of gene array data from irradiated human marrow endothelial cells and hematopoietic progenitor cells. Identify dynamic changes in circulatory blood cell counts, bone marrow cellularity and ileum structure morphology after radiation-wound combined injury with or without ghrelin. Evaluate mTOR-AKT signaling and MAPK signaling in bone marrow cells and ileum after exposure to gamma-radiation combined with hemorrhage. Assess modulation and correlation of cytokine profiles in serum and ileum after ghrelin therapy in order to find key cytokine(s) that is/are associated with ileal recovery after CI. Evaluate cytokine changes after gamma irradiation at various radiation dose rates. Verify identity and complex kinetics of MAPkinase pathway intermediates activated by virus in macrophages. Determine identity and kinetics of MAPkinase pathway intermediates by IR and combined exposure. Determine whether AKT pathway is activated by radiation and combined radiation virus exposure. Complete characterization of reporter cells as alternate interferon assay method for general use. Conduct experiments using dual reporter cells and pathway inhibitors to gain additional insight into differential gene promoter activation after combined radiation and virus exposure. Use macrophages with and without transgene reporters to gain insights into best timing of MAPK inhibitor control of radiation induced cytokine and chemokine production. Determine effects on IR and combined exposures on production of Type I interferon by macrophages. Complete development of oxidation-sensitive drug delivery system tuned to degrade at rate corresponding to level of oxidants present within microenvironment of cell. Complete development of multi-photon-responsive nanocarrier designed to respond to UV light, near infrared (NIR) light and IR. Identify histone modifications associated with radiation exposure and determine whether dose, dose rate, or radiation quality affect different modifications. Using bioinformatics, identify gene signaling pathway (s) most associated with low dose radiation delayed effects. Establish cell model system and low dose exposure linked to specific low dose cancer biomarkers in epigenome that can be targeted for countermeasure development. Examine these chemical modifications/biomarkers as they change depending on the dose, dose rate, or type of radiation. Fully evaluate the ability of on demand release nanoparticles and radiation induced release nanoparticles to modulate gene activation of multiple gene reporter cells. Evaluate the nanoparticle release of MAPKase inhibitors to modulate radiation and combined injury induction of cytokine and chemokines. Evaluate the nanoparticle deliver of small molecule modulators on ex vivo macrophages specifically murine bone marrow derived and human macrophages exposed to radiation. Develop collaborative efforts with DoD and HHS Institutes (USACEHR and NCATs) to establish a drug screening approach in the Intramural Screening Program. Determine optimum dose and schedule for PrC-210 to achieve optimum radioprotective survival efficacy. Determine the effect of PrC-210 on accelerating recovery from radiation-induced peripheral blood cytopenia and bone marrow damage. Determine optimum schedule of subcutaneous administration (prophylactic) of TPOm and BBT-059 at optimum dose to achieve optimum radioprotective survival efficacy. Determine dose-reduction factor of TPOm and BBT-059 with optimum dose and time. Demonstrate the effect of BBT-059 in protecting bone marrow progenitor cells from radiation damage. Evaluate the effect of TPOm on endothelial dysfunction markers (Thrombomodulin, ICAM-1, Endothelin-1, E-Selectin, MMP-9, sVCAM-1 and PAI-1) in mouse serum. Evaluate the effect of TPOm in inducing cytokines/chemokines using a 23-plex cytokine luminex assay. Evaluate the radiation-induced long non-coding RNAs (lncRNAs) in mouse spleen and study the effect of CDX-301. Study the down-stream proteins of ERK, MAP2K, and Smad2/3 pathway using western blot in mouse spleen and jejunum and test the effect of CDX-301. Screen three new drugs (acquired through NIAID NCEA) in mouse model for their radiation countermeasure potential			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241C / *Radiation Countermeasures (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018

(prophylactic). Continue to perform ghrelin mechanism on survival improvement after combined injury. Continue to evaluate radiation effects in minipigs. Continue to evaluate in vitro mesenchymal stem cell responses to radiation through network of AKT-MAPK cross talk and mTOR-Wnt interaction.

FY 2018 Plans:

Continue murine leukemia model to concomitantly predict leukemia development based on epigenetic markers identified in FY16 and FY17 at low and high doses. Continue lifespan study to continue evaluation of dual benefit radiation mitigation of both acute and delayed effects. Test new candidates under Intramural screening program (ISP) in collaboration with NCATs. Screen five new drugs (acquired through NIAID NCEA) in mouse model for their radiation countermeasure potential (prophylactic). Study mechanism of action of promising drugs using primary and transformed cell lines. Develop BBT-059 in mouse model administered shortly after radiation. Test promising countermeasure candidates in irradiated gut and/or lung mouse model. Understand long term effects of acute radiation exposure in in surviving mice. Will evaluate effects of ghrelin treatment in survival of minipigs or NHP after irradiation. Will continue to evaluate effects of combined drugs on H-ARS and GI-ARS in irradiated and combined injured mice. Will gather sufficient data to provide insight of radiation sensitivity variations among species. Will extend mechanistic elucidation to lungs. Determine whether modulation of the radiation-virus induced inflammatory response is best inhibited by use of broad MAPkinase inhibitors or ones selective for specific targeted pathway intermediates. Determine details of the MAPK and IRF pathway signaling pathways in human ex vivo macrophages and the response during combined exposure to ionizing radiation and FLUA. Determine the effects of additional anti-oxidants and other response modifiers of radiation, infectious disease inflammatory stimulation and combined injury which result in activation of the stable transcription factor reporters. Extend currently characterized gene-promoter reporter cells to understand the gene activation of radiation exposure combined with LPS (bacterial) exposure. Determine the level and kinetic changes of oxygen free radical species in reporter gene cells in response to different qualities and rates of ionizing radiation. Conduct pilot study of ionizing radiation effect on cell lines having unique oxidative and virus resistance profiles. Continue murine leukemia model to concomitantly predict leukemia development based on epigenetic markers identified in FY16 and FY17 at low and high doses. Continue lifespan study to continue evaluation of dual benefit radiation mitigation of both acute and delayed effects. Test new candidates under Intramural screening program (ISP) in collaboration with NCATs. Screen five new drugs (acquired through NIAID NCEA) in mouse model for their radiation countermeasure potential (prophylactic). Study mechanism of action of promising drugs using primary and transformed cell lines. Develop BBT-059 in mouse model administered shortly after radiation. Test promising countermeasure candidates in irradiated gut and/or lung mouse model. Understand long term effects of acute radiation exposure in in surviving mice. Will evaluate effects of ghrelin treatment in survival of minipigs or NHP after irradiation. Will continue to evaluate effects of combined drugs on H-ARS and GI-ARS in irradiated and combined injured mice. Will gather sufficient data to provide insight of radiation sensitivity variations among species. Will extend mechanistic elucidation to lungs. Determine whether modulation of the radiation-virus induced inflammatory response is best inhibited by use of broad MAPkinase inhibitors or ones selective for specific targeted pathway intermediates. Determine details of the MAPK and IRF pathway signaling pathways in human ex vivo macrophages and

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241C / *Radiation Countermeasures (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
the response during combined exposure to ionizing radiation and FLUA. Determine the effects of additional anti-oxidants and other response modifiers of radiation, infectious disease inflammatory stimulation and combined injury which result in activation of the stable transcription factor reporters. Extend currently characterized gene-promoter reporter cells to understand the gene activation of radiation exposure combined with LPS (bacterial) exposure. Determine the level and kinetic changes of oxygen free radical species in reporter gene cells in response to different qualities and rates of ionizing radiation. Conduct pilot study of ionizing radiation effect on cell lines having unique oxidative and virus resistance profiles. Develop new candidates in mouse model under Intramural screening program in collaboration with NCATs. Screen five new drugs (acquired through NIAID NCEA) in mouse model for their radiation countermeasure potential (prophylactic). Test promising countermeasure candidates in irradiated gut and/or lung mouse model. Study mechanism of action of promising drugs using primary and transformed cell lines. Elucidate the signal transduction pathways for promising drugs. Understand long term effects of acute radiation exposure in surviving mice. Will determine the lead combined drugs on mitigating H-ARS and GI-ARS in mice. Will elucidate molecularly the lead combined drugs on mitigating H-ARS in mice. Determine details of the upstream MAPK and IRF pathway intermediates in human ex vivo macrophages and the response during combined exposure to ionizing radiation and FLUA. Determine the identity and kinetics cytokine and chemokine production by combine exposure to LPS (bacterial) exposure. Determine the effects of combined ionizing radiation and LPS exposures on activation and kinetics for NFkB and MAPK in macrophages. Use currently characterized gene-promoter reporter cells to understand differences in gene activation by different qualities of radiation exposure notably gamma versus neutron and mixed-field exposures. Pilot studies on using cell reporter assays as high throughput systems (HTS) to identify off target effects of radiation countermeasure(s) during radiation and combined injury exposures. Develop new candidates in mouse model under Intramural screening program in collaboration with NCATs. Screen five new drugs (acquired through NIAID NCEA) in mouse model for their radiation countermeasure potential (prophylactic). Test promising countermeasure candidates in irradiated gut and/or lung mouse model. Test promising countermeasure candidates in mixed field radiation. Understand the mechanism of action of promising candidates using primary and transformed cell lines. Will determine the lead combined drugs on mitigating H-ARS and GI-ARS in minipigs or NHP. Will continue to elucidate molecularly the lead combined drugs on mitigating GI-ARS in mice. Determine the effects of combined ionizing radiation and LPS exposures on activation of NFkB and MAPK in in human ex vivo macrophages. Determine if upstream events activating transcription factors in reporter gene cells differ for different qualities and dose rates of ionizing radiation. Develop new candidates in mouse model under Intramural screening program in collaboration with NCATs. Screen five new drugs (acquired through NIAID NCEA) in mouse model for their radiation countermeasure potential (prophylactic). Test promising countermeasure candidates in irradiated gut and/or lung mouse model. Test promising countermeasure candidates in mixed field radiation. Understand the mechanism of action of promising candidates using primary and transformed cell lines. Will elucidate molecularly the lead combined drugs on mitigating H-ARS in minipigs or NHP. Will elucidate molecularly the lead combined drugs on mitigating GI-ARS in minipigs or NHP. Determine combinations of response NFkB and MAPK response modifiers for control of LPS and radiation induced cytokines and chemokines. Determine NFkB and MAPK activation and cytokine and chemokine production during sequential combined radiation-virus-LPS exposures.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241C / *Radiation Countermeasures (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Determine the panel of gene reporter cells and methodologies to use this system for identification of on and off target effects of radiation countermeasures.			
Accomplishments/Planned Programs Subtotals	0.779	0.855	0.916

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY 2016

- Complete evaluation of micro-RNA profile in mouse serum after radiation alone and combination with wound trauma.
- Complete evaluation of molecular mechanisms involved in radiation, wounding, hemorrhage, and/or combined injury.
- Complete publication of combined injury model with radiation followed by hemorrhage.
- Complete identification and kinetics of MAPKinase signaling pathway molecules which are activated by IR-virus combined injury.
- Complete evaluation of gene activation reporter cells as new and novel Type I interferon assay.
- Complete assessment of current nanoparticle constructs ability to modulate macrophage inflammatory responses to radiation.
- Measure miRNAs differentially expressed after low dose radiation exposure and low dose rates.
- Conduct experiments using gamma, x-ray, alpha, and neutron sources and measure histone modifications in early, mid, and late neoplastic clones.
- Assess non-targeted radiation effects in co-cultured cells that transform to malignant cells following high LET radiation, assess magnitude following low LET radiation.
- Conduct low dose x-ray radiation fractionated exposures, compare to a single high dose exposure, and determine whether multiple exposures of low dose radiation induced different malignancy rates than single higher total dose.

By FY 2017

- Identify novel countermeasures from drug screening.
- Continue to identify dynamic changes in circulatory blood cell counts, bone marrow cellularity and ileum structure morphology after radiation-wound combined injury.
- Complete evaluation of mTOR-AKT signaling and MAPK signaling in ileum and ileal morphology after exposure to gamma-radiation combined with hemorrhage.
- Complete assessment of modulation and correlation of cytokine profiles in serum and ileum after ghrelin therapy in order to find key cytokine(s) associated with ileal recovery after CI.
- Begin to measure cytokines, CRP, C3, IgM, PGE2, and Flt-3 ligand in serum of minipigs after Co-60 irradiation.

- Begin to measure cytokines, CRP, C3, IgM, PGE2, and Flt-3 ligand in serum of mice after Co-60 irradiation at various dose rates. Preliminary data show that high radiation dose at very low dose rate fails to alter cytokine concentrations.
- Complete assessment of timing and duration of effects of MAPK pathway inhibitors on inflammatory macrophages exposed to radiation.
- Complete assessment of ex vivo human macrophage response to IR, viral infection, and combined injury.
- Complete assessment of transcription factor reporter cells to test biological response modulators of gene activation induced by IR, microbial agonists, and combined exposures.
- Complete development of oxidation-sensitive drug delivery system tuned to degrade at rate corresponding to level of oxidants present within microenvironment of cell.
- Complete development of multi-photon-responsive nanocarrier designed to respond to UV light, near infrared (NIR) light, and IR.
- Complete assessment of nanoparticle constructs' ability to modulate macrophage inflammatory responses to combined radiation-microbial agonist exposures.
- Identify and measure early epigenomic steps in post-radiation process caused by low dose gamma radiation and low dose rates to stem cell populations.
- Identify specific histone modifications associated with low LET radiation (gamma or x-ray) compared to high LET radiation (alpha or neutron) at multiple dose rates and low doses.
- Identify specific DNA modifications associated with low LET radiation (gamma or x-ray) compared to high LET radiation (alpha or neutron) at multiple dose rates and low doses.
- Measure effects of low doses (<100 cGy) at different dose rates (34 µGy to 10 cGy/min) on neural stem (NSC) cell potential, DNA damage, histone acetylation/ methylation, and DNA methylation. Compare radiation qualities (x-ray/LINAC, gamma, alpha particle, and neutrons).
- Measure effects of low doses (<100 cGy) at different dose rates (34 µGy to 10 cGy/min) on mesenchymal stem cell (MSC) potential, DNA damage, histone acetylation/ methylation, and DNA methylation.
- Measure effects of low doses of gamma (<100 cGy) at different dose rates (34 µGy to 10 cGy/min) on MSC in vivo, evaluating DNA damage, histone acetylation/ methylation, and DNA methylation.
- Measure effects of low doses of alpha particles (<100 cGy) at different dose rates (34 µGy to 10 cGy/min) on MSC in vivo.

By FY 2018
- Test new potential drugs as radiation countermeasures.
- Continue to measure cytokines, CRP, C3, IgM, PGE2, and Flt-3 ligand in serum of minipigs after Co-60 irradiation.
- Continue to measure cytokines, CRP, C3, IgM, PGE2, and Flt-3 ligand in serum of mice after Co-60 irradiation at various dose rates.
- Continue to measure cytokines in spleen and bone marrow of mice after mixed field irradiation to study differential effects of genders and radiation dose rate.
- Correlate mTOR-AKT and MAPK signaling network and ATP production after in vitro radiation-burn combined injury.
- Evaluate mTOR-AKT signaling and MAPK signaling in ex vitro bone marrow mesenchymal cells and in vitro small intestine cells after exposure to gamma-radiation combined with burn trauma for determining survival signaling.
- Complete assessment of ex vivo human macrophage response to IR, viral infection and combined injury.
- Complete assessment of timing and duration of using MAPK pathway inhibitors to alter inflammatory macrophages exposed to radiation.
- Complete determination of effect of IR on cell signaling pathways that control production of Type I interferon.
- Establish novel cell model system to examine specific low dose cancer biomarkers in the epigenome that can be targeted for countermeasure development.
- Establish methylation and histone-regulated reporter plasmids, test for responsiveness to IR.

- Initiate low dose and dose-rate studies to test reporter plasmid assays to determine potential use to identify new countermeasures based on specific epigenomic changes.
- Use bioinformatics to identify gene signaling pathway(s) most associated with low dose radiation-induced neoplasia in vitro.
- Complete DRF (dose reduction factor) of TPOm and BBT-059
- Study the effect of TPOm on radiation-induced endothelial dysfunction
- Study the downstream effect of CDX-301 on signaling targets of ERK, MAP2K, and Smad2/3
- Identify lncRNAs in spleen from mice treated with CDX-301
- Identify novel countermeasures from drug screening
- Complete identification of MAPkinase pathway intermediates by ionizing radiation and ionizing radiation-virus combined injury.
- Complete evaluation of gene activation reporter cells as new and novel Type I interferon assay.
- Complete assessment of transcription factor reporter cells to test biological response modulators of gene activation induced by ionizing radiation, microbial agonists and combined exposures.
- Complete assessment of current nanoparticle constructs ability to modulate macrophage inflammatory responses to radiation.

By FY 2018

- Initiate murine leukemia model and measure multiple epigenetic markers in serum and WBCs after exposure to low and high doses and a low versus high dose rate
- Initiate mouse lifespan study to induce ARS and provide countermeasure and then to continue countermeasure to assess development of delayed radiation effects including leukemia and thymic tumors
- Understand the molecular pathways involved in the radioprotection by TPOm and BBT-059
- Understand the molecular pathways involved in the radioprotection by BBT-059
- Understand the effect of PrC-210 on recovery of radiation-induced depletion of peripheral blood cells and bone marrow progenitor cells
- Test new potential drugs as radiation countermeasures
- Continue to identify dynamic changes in circulatory blood cell counts, bone marrow cellularity and ileum structure morphology after radiation-wound combined injury.
- Complete evaluation of mTOR-AKT signaling and MAPK signaling in ileum and ileal morphology after exposure to gamma-radiation combined with hemorrhage.
- Complete assessment of modulation and correlation of cytokine profiles in serum and ileum after ghrelin therapy in order to find key cytokine(s) associated with ileal recovery after CI.
- Begin to measure cytokines, CRP, C3, IgM, PGE2, and Flt-3 ligand in serum of minipigs after Co-60 irradiation.
- Begin to measure cytokines, CRP, C3, IgM, PGE2, and Flt-3 ligand in serum of mice after Co-60 irradiation at various dose rates. Preliminary data show that high radiation dose at very low dose rate fails to alter cytokine concentrations.
- Complete measurement of kinetics of MAPKinase signaling pathway molecules which are activated by ionizing radiation-virus combined injury.
- Complete kinetic profile for radiation modulation of Type I interferon production
- Complete development of an oxidation-sensitive drug delivery system that is tuned to degrade at a rate corresponding to the level of oxidants present within the microenvironment of the cell.
- Complete development a multi-photon-responsive nanocarrier designed to respond to UV light, near infrared (NIR) light and ionizing radiation (IR).

- Complete initial studies for using nanoparticules to modulate inflammatory responses to radiation exposure.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241C / *Radiation Countermeasures (USUHS)*

- Complete assessment of nanoparticle constructs ability to modulate macrophage inflammatory responses to combined radiation-microbial agonist exposures.

By FY 2019

- Assess leukemia development concomitantly with measurement of multiple epigenetic markers in serum and WBCs using microarray technology
- Assess leukemia development in mice recovered from ARS but receiving late effects countermeasure; use necropsy to determine cause of death.
- Test promising candidates in mixed field
- Test promising candidates after exposure to gut using SARRP
- Identify new potential drugs as radiation countermeasures

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Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603002DHA *I Medical Advanced Technology (AFRRI)*

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
Total Program Element	1.559	0.282	0.310	0.332	-	0.332	0.338	0.345	0.352	0.359	Continuing	Continuing
030A: *CSI - Congressional Special Interests*	0.031	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
242A: *Biodosimetry (USUHS)*	0.918	0.169	0.186	0.199	-	0.199	0.202	0.206	0.210	0.214	Continuing	Continuing
242B: *Radiation Countermeasures (USUHS)*	0.610	0.113	0.124	0.133	-	0.133	0.136	0.139	0.142	0.145	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences/ Armed Forces Radiobiology Research Institute (USUHS/AFRRI), this program supports applied research for advanced development of biomedical strategies to prevent, treat and assess health consequences from exposure to ionizing radiation. It capitalizes on findings under PE 0602787HP, Medical Technology, and from industry and academia to advance novel medical countermeasures into and through pre-clinical studies toward newly licensed products. Program objectives focus on mitigating the health consequences from exposures to ionizing radiation(alone or in combination with other injuries) that represent the highest probable threat to US forces in current tactical, humanitarian and counterterrorism mission environments. Findings from basic and developmental research are integrated into focused advanced technology development studies to produce the following: (1) protective and therapeutic strategies; (2) novel biological markers and delivery platforms for rapid, field-based individual medical assessment; and (3) experimental data needed to build accurate models for predicting casualties from complex injuries involving radiation and other battlefield insults. The AFRRI, because of its multidisciplinary staff and exceptional laboratory and radiation facilities, is uniquely positioned to execute the program as prescribed by its mission.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	0.305	0.310	0.332	-	0.332
Current President's Budget	0.282	0.310	0.332	-	0.332
Total Adjustments	-0.023	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.023	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 030A: *CSI - Congressional Special Interests*		
Congressional Add: *473A – Program Increase: Restore Core Research Funding Reduction (USUHS)*	0.000	-

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603002DHA *I Medical Advanced Technology (AFRRI)*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Congressional Add Subtotals for Project: 030A	0.000	-
Congressional Add Totals for all Projects	0.000	-

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603002-Advanced Technology (AFRRI) (-$0.024 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$0.024 million).

FY 2015: Restore core research funding to the DHP RDT&E, PE 0603002-Advanced Technology (AFRRI) (+$0.031 million).

FY 2016: No Change.

FY 2017: No Change.

FY 2018: No Change.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603002DHA / *Medical Advanced Technology (AFRRI)*	**Project (Number/Name)** 030A / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
030A: *CSI - Congressional Special Interests*	0.031	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY15 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0603002 - Medical Advanced Technology (AFRRI). Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 473A – Program Increase: Restore Core Research Funding Reduction (USUHS)	0.000	-
FY 2016 Accomplishments: No Funding Programmed.		
Congressional Adds Subtotals	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603002DHA / *Medical Advanced Technology (AFRRI)*	Project (Number/Name) 242A / *Biodosimetry (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
242A: *Biodosimetry (USUHS)*	0.918	0.169	0.186	0.199	-	0.199	0.202	0.206	0.210	0.214	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences/Armed Forces Radiobiology Research Institute (USU/AFRRI), this program supports applied research for advanced development of biomedical strategies to prevent, treat and assess health consequences from exposure to ionizing radiation. It capitalizes on findings under PE 0602787HP, Medical Technology, and from industry and academia to advance novel medical countermeasures into and through pre-clinical studies toward newly licensed products. Program objectives focus on mitigating the health consequences from exposures to ionizing radiation (alone or in combination with other injuries) that represent the highest probable threat to US forces in current tactical, humanitarian and counterterrorism mission environments. Findings from basic and developmental research are integrated into focused advanced technology development studies to produce the following: (1) protective and therapeutic strategies; (2) novel biological markers and delivery platforms for rapid, field-based individual medical assessment; and (3) experimental data needed to build accurate models for predicting casualties from complex injuries involving radiation and other battlefield insults. The AFRRI, because of its multidisciplinary staff and exceptional laboratory and radiation facilities, is uniquely positioned to execute the program as prescribed by its mission.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Biodosimetry (USUHS)	0.169	0.186	0.199

Description: Biodosimetry (USUHS): For the Uniformed Services University of the Health Sciences (USUHS), this program supports applied research for advanced development of biomedical and biophysical strategies to assess health consequences from exposure to ionizing radiation. It capitalizes on findings under PE 0602787HP, Medical Technology, and from industry and academia to advance novel biological markers and delivery platforms for rapid, field-based individual dose assessment and experimental data needed to build accurate models for predicting casualties from complex injuries involving radiation and other battlefield insults.

FY 2016 Accomplishments:

Contributed efforts using radiation-responsive biomarkers in higher order animal and human models for diagnostic biodosimetry applications; developed and reported on algorithm using multiple human blood cell types (i.e., lymphocytes, neutrophils, platelets) for radiation dose assessment. Participated in several exercises successfully demonstrating ability to report rapidly on dose assessment using cytogenetic chromosome-aberration assay; reported on status of AFRRI's cytogenetic biodosimetry capability for dose assessment using metaphase-spread dicentric chromosome aberration and premature chromosome condensation assays. Developed and applied radiation risk and injury categorization (RRIC) algorithm using hematology and serum chemistry parameters for triaging minipigs exposed to TBI lethal and nonlethal radiation doses between days 0-30 days; compared minipig and non-human primate RRIC models. Sustained efforts to provide DOD end-users improved radiation diagnostic tools; maintained access to diagnostic worksheets and software applications on Institute's Biodosimetry Tools website; and transitioned WinFRAT software application for use on smart phones (Mobile FRAT). Reported on current status and utility for use of emerging

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603002DHA / *Medical Advanced Technology (AFRRI)*	**Project (Number/Name)** 242A / *Biodosimetry (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
biodosimetry assays on DOD's concept of operations for biodosimetry tools in operational environments. Participated in first exercise and successfully used early-phase clinical signs and symptoms for triaging suspected radiation patients based on results from human radiation accident registry. Contributed in efforts to justify establishment and design of scope of operations for DOD Biodosimetry Network to provide multiple parameter biodosimetry capability. Completed 4 mouse experiments using special housing partition chambers for prolonged irradiations that had not been used before. Mouse experiments completed used lower dose rates than had been used previously, with irradiations lasting up to 3 hours. ***FY 2017 Plans:*** Sustain efforts to develop and validate biodosimetry tools useful in operational environments. Establish use of PCC assay for assessment of partial-body exposure including use of protein nucleic acid (PNA) centromeric probes for identification of dicentric aberrations in PCC assay; expand upon radiation calibration curves using PCC assay. Sustain participation in exercises and establishment of clinical laboratory certification.Initiate efforts via collaboration with NATO collaborator to establish and evaluate baboon radiation dose-response database archive for use in extending radiation risk and injury categorization (RRIC) algorithm. Report on nonhuman primate radiation dose response and acute radiation syndrome scoring system. Develop enhancements (ARS severity score) to DOD radiation diagnostic software tools useful for military applications. Evaluate effects of radioprotectant on radiation risk categorization (RRIC) algorithm based on blood counts and blood chemistries using irradiated nonhuman primate archived data. Assess cytokines in sera from mice irradiated at low dose rate in FY2016. ***FY 2018 Plans:*** Continue evaluation of baboon radiation biomarker database utility to predict hematopoietic acute radiation syndrome severity. Perform internal assessment of quality control program for dose assessment by cytogenetics in support of clinical laboratory certification. Develop algorithm using blood cell counts and biochemical biomarkers in NHP radiation dose response model. Initiate efforts to evaluate blood samples from human radiation therapy patients using panel of radiation-responsive biomarkers. Evaluate effects of radioprotectant on radiation risk categorization (RRIC) algorithm based on blood counts and blood chemistries using irradiated nonhuman primate archived data. Perform and report on an evaluation to validate the utility of the human biomarker model. Delivery an updated software tools incorporating human radiation risk and dose tool. Report on laboratory's competence in inter-comparison exercises for radiation dose assessment. Report on recent developments and use of AFRRI's Biodosimetry Tools. Obtain CLIP certification for performance of the dicentric assay for dose assessment. Report on use of AFRRI's suite of biodosimetry tools in a radiological exercise.			
Accomplishments/Planned Programs Subtotals	0.169	0.186	0.199

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603002DHA / *Medical Advanced Technology (AFRRI)*	**Project (Number/Name)** 242A / *Biodosimetry (USUHS)*

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY 2016
- Report on current status of AFRRI's capability and capacity to perform dose assessment by cytogenetics.
- Participate in annual performance evaluations to demonstrate accuracy in dose assessment by cytogenetics.
- Continue studies evaluating new radiation-responsive biomarkers in animal models for early-phase and organ-specific damage and their applicability in humans.
- Continue to create human baseline database for evaluated biomarkers for use in human radiation accident cases.
- Release Mobile FRAT smart phone apps for iPhone and Android operating systems.

By FY 2017
- Report on development and use of AFRRI's FRAT application for utility in triage diagnostics of suspected radiation casualties.
- Test ability of PCC assay for assessment of high-dose partial-body exposures.
- Continue evaluating new predictive radiation-responsive biomarkers in NHP models for ARS outcome and their applicability in humans.
- Continue to create human baseline database for evaluated biomarkers for use in human radiation accident cases.
- Establish large animal models (i.e., baboon, Rhesus monkey) radiation biomarker database archive linked to severity of acute radiation syndrome.

By FY2018
- Model radiation risk and injury categorization (RRIC) algorithm using large animal models (i.e., baboon, Rhesus monkey) radiation dose response databases to predict hematopoietic ARS; initiate comparison of RRIC algorithm with human radiation accident data.
- Report use of multiple radiation-responsive endpoints using premature chromosome condensation assay for radiation dose assessment.
- Provide enhanced and updated radiation software application.

By FY2019
-Perform and report on an evaluation to validate the utility of the human biomarker model.
-Delivery an updated software tools incorporating human radiation risk and dose tool.
-Report on laboratory's competence in inter-comparison exercises for radiation dose assessment.
- Report on recent developments and use of AFRRI's Biodosimetry Tools.

By FY2020
- Obtain CLIP certification for performance of the dicentric assay for dose assessment.
- Report on use of AFRRI's suite of biodosimetry tools in a radiological exercise.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603002DHA / *Medical Advanced Technology (AFRRI)*	Project (Number/Name) 242B / *Radiation Countermeasures (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
242B: *Radiation Countermeasures (USUHS)*	0.610	0.113	0.124	0.133	-	0.133	0.136	0.139	0.142	0.145	Continuing	Continuing

A. Mission Description and Budget Item Justification

Radiation Countermeasures (USU): For the Uniformed Services University of the Health Sciences (USU), this program supports applied research for advanced development of biomedical strategies to prevent and treat health consequences from exposure to ionizing radiation. It capitalizes on findings under PE 0602787HP, Medical Technology, and from industry and academia to advance novel medical countermeasures into and through pre-clinical studies toward newly licensed products. Program objectives focus on preventing or mitigating the health consequences from exposures to ionizing radiation alone or in combination with other injuries, in the context of probable threats to US forces in current tactical, humanitarian and counterterrorism mission environments. Findings from basic and developmental research are integrated into highly focused advanced technology development studies yielding protective and therapeutic strategies.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Radiation Countermeasures (USUHS)	0.113	0.124	0.133

Description: Radiation Countermeasures (USU): For the Uniformed Services University of the Health Sciences (USU), this program supports applied research for advanced development of biomedical strategies to prevent and treat health consequences from exposure to ionizing radiation. It capitalizes on findings under PE 0602787HP, Medical Technology, and from industry and academia to advance novel medical countermeasures into and through pre-clinical studies toward newly licensed products. Program objectives focus on preventing or mitigating the health consequences from exposures to ionizing radiation alone or in combination with other injuries, in the context of probable threats to US forces in current tactical, humanitarian and counterterrorism mission environments. Findings from basic and developmental research are integrated into highly focused advanced technology development studies yielding protective and therapeutic strategies.

FY 2016 Accomplishments:

Evaluated efficacy biomarkers of Ex-RAD using in vitro and mouse models. Several pathway molecules identified. Evaluated and compared prophylactic efficacy of DeltaGold® (American River Nutrition) with gamma-tocotrienol, as single dose administered subcutaneously in mouse model and found to be as efficacious. Evaluated toxicity and established prophylactic efficacy of single dose of PrC-210 (aminothiol analog of amifostine, WR 2721), administered orally, in mouse model as radioprotectant. Established and confirmed radioprotective prophylactic efficacy of TPOm (a thrombopoietin mimetic, RWJ-800088, Janssen R&D) and BBT-059 (PEGylated IL-11 analog, Bolder Biotech Inc.), administered subcutaneously in mouse model. Determined optimum drug dose of TPOm and BBT-059 to achieve optimum prophylactic efficacy. Demonstrated accelerating recovery from radiation-induced peripheral blood cytopenia with both TPOm and BBT-059. Demonstrated effect of TPOm in protecting bone marrow progenitor cells from radiation damage. Evaluated differentially regulated radiation-induced microRNAs in serum with or without CDX-301 treatment, identifying 4 target signaling pathways (ERK, MAP2K, Smad2/3 and insulin) from IPA network

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603002DHA / *Medical Advanced Technology (AFRRI)*	**Project (Number/Name)** 242B / *Radiation Countermeasures (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
analysis. Determined efficacy of CDX-301 in gastrointestinal recovery after radiation exposure. Completed evaluation of efficacy of combined pharmaceutical regimen against radiation combined injury (irradiation followed immediately by skin wound trauma). Completed determination of effectiveness of combined therapy of G-CSF and ALXN4100TPO, a thrombopoietin receptor agonist, to mitigate or inhibit long-term deleterious responses to radiation combined injury. Completed determination of effectiveness of combined therapy of peg-G-CSF and ALXN4100TPO, a thrombopoietin receptor agonist, to mitigate or inhibit long-term deleterious responses to radiation combined injury. Completed preparation of peg-G-CSF experiment with irradiation immediately followed by skin wound trauma. PGC-1 (a regulator for NF-kB) was upregulated in ileum of combined injured mice on day 1. Similarly, Nrf-2 (a stimulator for ATP production) was increased as well. ***FY 2017 Plans:*** Determine optimum dose and schedule for PrC-210 to achieve optimum radioprotective survival efficacy. Determine dose-reduction factor of PrC-210 with optimum dose and time. Determine effect of PrC-210 on accelerating recovery from radiation-induced peripheral blood cytopenia. Determine optimum schedule of subcutaneous administration (prophylactic) of TPOm and BBT-059 at optimum dose to achieve optimum radioprotective survival efficacy. Determine dose-reduction factor of TPOm and BBT-059 with optimum dose and time. Demonstrate effect of BBT-059 in protecting bone marrow progenitor cells from radiation damage. Evaluate effect of TPOm on endothelial dysfunction markers (Thrombomodulin, ICAM-1, Endothelin-1, E-Selectin, MMP-9, sVCAM-1 and PAI-1) in mouse serum. Evaluate effect of TPOm in inducing cytokines/chemokines using 23-plex cytokine Luminex assay. Evaluate radiation-induced long non-coding RNAs (lncRNAs) in mouse spleen and study effect of CDX-301. Study down-stream proteins of ERK, MAP2K, and Smad2/3 pathway using western blot in mouse spleen and jejunum and test effect of CDX-301. Evaluate toxicity and survival efficacy of phenyl butyrate in mouse model for prophylactic radiation countermeasure. Conduct the peg-G-CSF experiment with irradiation immediately followed by skin wound trauma. Continue to perform PGC-1α, NF-#B, and MAPK on radiation sensitivity variations among species. ***FY 2018 Plans:*** Continue to elucidate mechanisms underlying radioprotective efficacy by CDX-301. Continue to discover mechanisms of TPOm on survival improvement after radiation by profiling cytokine/chemokine and signal transduction pathway activation, and miRNA regulation. Demonstrate effect of PrC-210 in protecting bone marrow progenitor cells from radiation damage. Investigate mechanisms of BBT-059 on survival improvement after radiation by profiling cytokine/chemokine and signal transduction pathway activation, and miRNA regulation. Will continue to gather data on cytokine concentrations to understand radiation sensitivity variations among species. Will continue to gather data on Nrf and ATP levels to understand radiation sensitivity variations among species. Will gather data on mitochondrial remodeling to understand radiation sensitivity variations among species. Will gather data on miRNA-696 dynamic changes to understand radiation sensitivity variations among species. Will analyze and integrate data to provide insight of radiation sensitivity variations among species, specifically biomarkers to indicate the sensitivity.			
Accomplishments/Planned Programs Subtotals	0.113	0.124	0.133

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603002DHA / *Medical Advanced Technology (AFRRI)*	**Project (Number/Name)** 242B / *Radiation Countermeasures (USUHS)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY 2016
- Continue biomarker identification for radiation countermeasure efficacy.
- Determine whether efficacy of DeltaGold® and gamma-tocotrienol is comparable.
- Test TPOm, BBT-059 and PrC-210 as potential radiation countermeasures in CD2F1 in mouse model.
- Assess accelerated recovery from peripheral blood cytopenia by TPOm and BBT-059.
- Predict miRNA targeted signaling pathways when treated with CDX-301 administered prior to radiation.
- Complete evaluation of therapeutic effects of G-CSF and ALXN4100TPO on survival after radiation combined injury.
- Complete evaluation of peg-G-CSF and Alxn4100TPO co-therapy after irradiation-wound combined injury.

By FY 2017
- Complete DRF (dose reduction factor) of TPOm, BBT-059 and PrC-210.
- Study effect of TPOm on radiation-induced endothelial dysfunction.
- Study downstream effect of CDX-301 on signaling targets of ERK, MAP2K, and Smad2/3
- Evaluate efficacy of Phenyl butyrate in CD2F1 mice.
- Identify lncRNAs in spleen from mice treated with CDX-301.
- Complete evaluation of peg-G-CSF and Alxn4100TPO co-therapy after irradiation-wound combined injury.
- Complete publication of peg-G-CSF and Alxn4100TPO co-therapy after irradiation-wound combined injury.
- Evaluate cellular PGC-1α, NF-#B, and MAPK measurements in spleen, ileum, lung, and heart of mice and minipigs after irradiation.

By FY 2018
- Understand molecular pathways involved in radioprotection by TPOm, BBT-059.
- Understand molecular pathways involved in radioprotection by BBT-059.
- Understand effect of PrC-210 on recovery of radiation-induced depletion of peripheral blood cells and bone marrow progenitor cells.
- Characterize dynamic changes in miRNA regulation in radiation-wound combined injured mice treated with ghrelin.
- Measure IL-18 and IL-BP in serum and various tissues in minipigs after 1.75 Gy.
- Measure cytokines and chemokines in serum and various tissues in mice after 9.5 Gy.

By FY 2019
- Evaluate Nrf1, Nrf2, and ATP in various tissues in minipigs after 1.75 Gy.
- Evaluate Nrf1, Nrf2, and ATP in various tissues in mice after 9.5 Gy.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603002DHA / *Medical Advanced Technology (AFRRI)*	**Project (Number/Name)** 242B / *Radiation Countermeasures (USUHS)*

By FY 2020
- Evaluate TFAM, DRP1, OPA1 and Mfn1 in various tissues in minipigs after 1.75 Gy.
- Evaluate TFAM, DRP1, OPA1 and Mfn1 in various tissues in mice after 9.5 Gy.

By FY 2021
- Evaluate miRNA-696 in serum and various tissues in minipigs after 1.75 Gy.
- Evaluate miRNA-696 in serum and various tissues in mice after 9.5 Gy.

By FY 2022
- Predict miRNA targeted signaling pathways using IPA in minipigs after 1.75 Gy.
- Predict miRNA targeted signaling pathways using IPA in mice after 9.5 Gy.
- Compare two species for their similarities and differences.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115DHA *I Medical Technology Development*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	3,657.398	1,261.030	220.916	245.936	-	245.936	274.920	269.421	269.473	274.476	Continuing	Continuing
300A: *CSI - Congressional Special Interests*	2,839.142	1,041.539	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
238C: *Enroute Care Research & Development (Budgeted) (AF)*	11.633	1.340	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
238D: *Core Enroute Care R&D - Clinical Translational Focus (AF)*	0.000	0.997	2.045	2.240	-	2.240	3.416	4.045	4.124	4.209	Continuing	Continuing
238E: *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.997	2.045	2.239	-	2.239	3.417	4.043	4.125	4.209	Continuing	Continuing
243A: *Medical Development (Lab Support) (Navy)*	128.420	35.878	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
247A: *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	0.200	2.060	2.064	1.548	-	1.548	0.000	0.000	0.000	0.000	0.000	5.872
247B: *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	0.425	1.040	1.135	1.238	-	1.238	0.000	0.000	0.000	0.000	0.000	3.838
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	8.545	1.700	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
284C: *Core Human Performance R&D - Clinical Translational Focus (AF)*	0.000	1.003	2.349	2.664	-	2.664	2.762	2.817	2.873	2.930	Continuing	Continuing
284D: *Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)*	0.000	1.002	2.348	2.663	-	2.663	2.761	2.816	2.872	2.929	Continuing	Continuing
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	16.914	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency										Date: May 2017		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115DHA *I Medical Technology Development*							
285B: *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	0.000	0.929	1.147	1.350	-	1.350	2.351	2.757	2.812	2.868	Continuing	Continuing
285C: *Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	0.928	1.147	1.349	-	1.349	2.351	2.757	2.812	2.868	Continuing	Continuing
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	40.028	6.920	7.725	5.034	-	5.034	5.135	5.237	5.342	5.449	Continuing	Continuing
307C: *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	0.000	0.545	1.500	2.235	-	2.235	2.295	2.341	2.388	2.435	Continuing	Continuing
307D: *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.400	1.500	2.235	-	2.235	2.295	2.341	2.388	2.435	Continuing	Continuing
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	12.160	1.180	1.160	1.560	-	1.560	1.591	1.623	1.655	1.689	Continuing	Continuing
308C: *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	0.000	1.503	1.500	1.497	-	1.497	1.527	1.557	1.589	1.620	Continuing	Continuing
308D: *Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	1.502	1.499	1.497	-	1.497	1.527	1.557	1.589	1.620	Continuing	Continuing
309A: *Regenerative Medicine (USUHS)*	22.296	8.775	7.323	7.373	-	7.373	8.327	10.209	10.413	10.621	Continuing	Continuing
373A: *GDF - Medical Technology Development*	395.744	113.011	139.454	126.790	-	126.790	136.578	138.564	147.876	152.262	Continuing	Continuing
378A: *CoE-Breast Cancer Center of Excellence (Army)*	32.949	6.750	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency										Date: May 2017		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115DHA *I Medical Technology Development*							
378B: *CoE-Breast Cancer Center of Excellence (USU)*	0.000	0.000	9.900	9.088	-	9.088	10.280	10.475	10.685	10.898	Continuing	Continuing
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	29.041	5.898	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
379B: *CoE-Gynecological Cancer Center of Excellence (USU)*	0.000	0.000	8.655	7.943	-	7.943	8.987	9.158	9.341	9.528	Continuing	Continuing
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	11.777	3.255	3.051	2.697	-	2.697	2.914	3.118	3.180	3.244	Continuing	Continuing
382A: *CoE-Pain Center of Excellence (Army)*	6.436	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
382B: *CoE-Pain Center of Excellence (USUHS)*	2.484	2.610	2.641	2.822	-	2.822	3.310	3.376	3.445	3.514	Continuing	Continuing
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	27.590	5.789	7.900	7.250	-	7.250	8.203	8.359	8.526	8.696	Continuing	Continuing
398A: *CoE-Neuroscience Center of Excellence (USUHS)*	3.679	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
429A: *Hard Body Armor Testing (Army)*	1.356	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
431A: *Underbody Blast Testing (Army)*	36.264	2.478	1.869	8.000	-	8.000	10.800	9.200	1.400	0.000	-	-
448A: *Military HIV Research Program (Army)*	11.933	6.093	6.070	6.359	-	6.359	7.360	7.877	8.035	8.196	Continuing	Continuing
830A: *Deployed Warfighter Protection (Army)*	18.382	4.908	4.889	5.123	-	5.123	5.930	6.345	6.473	6.601	Continuing	Continuing
478: *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*	0.000	0.000	0.000	14.766	-	14.766	14.754	18.556	18.639	18.724	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115DHA *I Medical Technology Development*							
479: *Framingham Longitudinal Study (USUHS)*	-	0.000	0.000	4.920	-	4.920	4.920	4.920	4.920	4.920	Continuing	Continuing
499: *MHS Financial System Acquisition*	-	0.000	0.000	13.456	-	13.456	21.129	5.373	1.971	2.011	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development: This program element (PE) provides funding for promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of Department of Defense and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research & Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include 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 (JPC-7), and clinical and rehabilitative medicine (JPC-8). As research efforts mature, the most promising will transition to advanced concept development funding, PE 0604110. For knowledge products, successful findings will transition into clinical practice guidelines.

For the Army Medical Command, the Underbody Blast (UBB) Testing medical research project provides funds to establish a scientific and statistical basis for evaluating skeletal injuries to vehicle occupants during ground vehicle UBB events. Areas of interest to the Secretary of Defense are medical research that provides an understanding of the human response and tolerance limits and injury mechanisms needed to accurately predict skeletal injuries to ground combat vehicle occupants caused by UBB events. This enhanced understanding will support the establishment of an improved capability to conduct Title 10 Live Fire Test and Evaluation and to make acquisition decisions.

For the Army Medical Command, the military human immunodeficiency virus (HIV) research project provides funds to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect military personnel from risks associated with HIV infection.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603115DHA *I Medical Technology Development*

For the Army Medical Command, the Armed Forces Pest Management Board Deployed Warfighter Protection program provides for the development of new or improved protection of military personnel from insects and tick vectors of disease pathogens.

For the Army Medical Command, three Centers of Excellence (CoE) receive medical technology development funds. Management of the Breast and Gynecological Cancer CoEs transfer from the Army to the Uniformed Services University beginning in FY 2017. The Cardiac Health CoE (Army) provides evidence-based personalized patient engagement approaches for comprehensive cardiac event prevention through education, outcomes research and technology tools, as well as molecular research to detect cardiovascular disease at an early stage to ultimately discover a signature for cardiovascular health, to find new genes that significantly increase risk for heart attack in Service members and other beneficiaries, and identify molecular markers of obesity and weight loss.

In FY 2016, Congressional Special Interest (CSI) funds were added to support peer-reviewed research programs: Amyotrophic Lateral Sclerosis (ALS), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis, Cancer, Lung Cancer, Orthopedic, Spinal Cord, Vision, Traumatic Brain Injury and Psychological Health (TBI/PH), Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer's, Reconstructive Transplant, Tuberous Sclerosis Complex, Duchenne Muscular Dystrophy, Epilepsy, and Tick-borne diseases. CSI funds were also provided for Joint Warfighter Medical Research, Orthotics and Prosthetics Outcomes, Trauma Clinic Research, HIV/AIDS Program Increase, Global HIV/AIDS Prevention, and Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

For the Navy Bureau of Medicine and Surgery, this program element includes funds for research management support costs. The Outside Continental US (OCONUS) laboratories conduct focused medical research on vaccine development for Malaria, Diarrhea Diseases, and Dengue Fever. In addition to entomology, HIV studies, surveillance and outbreak response under the Global Emerging Infections Surveillance (GEIS) program and risk assessment studies on a number of other infectious diseases that are present in the geographical regions where the laboratories are located. The CONUS laboratories conduct research on Military Operational Medicine, Combat Casualty Care, Diving and Submarine Medicine, Infectious Diseases, Environmental and Occupational Health, Directed Energy, and Aviation Medicine and Human Performance.

For the Air Force Medical Service (AFMS), medical research and development programs are divided into five primary thrust areas: En-Route care, Expeditionary Medicine, Operational Medicine (in-garrison care), Force Health Protection (FHP) (detect, prevent, threats), and Human Performance. Expeditionary Medicine is focused on care on the battlefield and in field hospitals prior to transporting patients out of theater to CONUS, and studies trauma resuscitation, hemorrhage control, and other life-saving interventions to keep critically wounded patients alive in the golden hour and to the next level of care. The AFMS is the only service transporting patients on long aeromedical evacuation missions. Therefore, the En-Route care thrust area studies include investigation on the impact of transport on patient and providers (including cabin altitude, noise, vibration, and environmental issues affecting physiology on the aircraft), patient safety factors during transport, medical technologies for use during transport, and research to support education and training with simulation for En-Route care providers. The Human Performance thrust area focuses on optimizing airmen physical and psychological performance, assessing the physical and cognitive demands on the operator (pilot/aircrew), facilitating a safe aviation environment through technology and equipment assessment, and improving/sustaining airmen performance through training. Medical development and biomedical technology investments in FHP seek to deliver an improved FHP capability across the full spectrum of operations with research that prevents injury/ illness through improved identification and control of health risks. Under FHP, sub-project areas include Occupational Hazard Exposure (Includes Flight Hazards and Integrated Risk), Targeted Risk Identification, Mitigation and Treatment (Formerly Pathogen ID and Novel Therapeutics and includes Big Data), FHP Technologies Development and Assessment (Assay and disease detection), and Health Surveillance, Infection, Injury & Immunity. FHP also includes Innovations and Personalized

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
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Medicine. Operational medicine is focused on in garrison care – our next most critical issue post OIF/OEF – and how to care for the whole patient and consideration of comorbidities in treatment of wounded warriors and dependents.

For the Uniformed Services University of the Health Sciences (USUHS), medical development programs include the Prostate Cancer Center of Excellence (CoE), the Center for Neuroscience and Regenerative Medicine (CNRM), the Pain CoE, the Breast Cancer CoE, and the Gynecological Cancer CoE. The Prostate CoE, formerly a CSI, was chartered in 1992 to conduct basic, clinical, and translational research programs to combat diseases of the prostate. The Center's mission is fulfilled primarily through its three principal programs -- the Clinical Translational Research Center, the Basic Science Research Program, and the Tri-Service Multicenter Prostate Cancer Database, which encompasses its clinical research work with other participating military medical centers. These affiliated sites contribute data and biospecimens obtained from prostate cancer patients who participate in clinical trials. CNRM brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to TBI research. CNRM research programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center. Beginning in FY17, the Breast Cancer CoE funding line and the Gynecological Cancer CoE funding line are transferred from the Army to USUHS.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	231.050	220.916	245.936	-	245.936
Current President's Budget	1,261.030	220.916	245.936	-	245.936
Total Adjustments	1,029.980	0.000	0.000	-	0.000
• Congressional General Reductions	-0.481	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	1,041.539	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-11.078	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 300A: *CSI - Congressional Special Interests*		
Congressional Add: *245A - Amyotrophic Lateral Sclerosis (ALS) Research*	7.500	-
Congressional Add: *293A - Autism Research*	7.500	-
Congressional Add: *296A - Bone Marrow Failure Disease Research*	3.000	-
Congressional Add: *310A - Peer-Reviewed Ovarian Cancer Research*	20.000	-
Congressional Add: *328A - Multiple Sclerosis Research*	6.000	-
Congressional Add: *335A - Peer-Reviewed Cancer Research*	50.000	-
Congressional Add: *336A - Peer-Reviewed Lung Cancer Research*	12.000	-

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
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Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Congressional Add: *337A - Peer-Reviewed Orthopedic Research*	30.000	-
Congressional Add: *338A - Peer-Reviewed Spinal Cord Research*	30.000	-
Congressional Add: *339A - Peer-Reviewed Vision Research*	10.000	-
Congressional Add: *352A - Traumatic Brain Injury/Psychological Health Research*	97.792	-
Congressional Add: *380A - Peer-Reviewed Breast Cancer Research*	120.000	-
Congressional Add: *390A - Peer-Reviewed Prostate Cancer Research*	80.000	-
Congressional Add: *392A - Gulf War Illness Peer-Reviewed Research*	20.000	-
Congressional Add: *396A - Research in Alcohol and Substance Use Disorders*	4.000	-
Congressional Add: *400A - Peer-Reviewed Medical Research*	278.700	-
Congressional Add: *417A - Peer-Reviewed Alzheimer Research*	15.000	-
Congressional Add: *439A - Joint Warfighter Medical Research*	30.000	-
Congressional Add: *452A - Peer-Reviewed Reconstructive Transplant Research*	12.000	-
Congressional Add: *454A - Orthotics and Prosthetics Outcomes Research*	10.000	-
Congressional Add: *456A - HIV/AIDS Program*	12.900	-
Congressional Add: *459A - Peer-Reviewed Epilepsy Research*	7.500	-
Congressional Add: *463A – Program Increase: Restore Core Research Funding Reduction (GDF)*	138.509	-
Congressional Add: *474A – Program Increase: Restore Core Research Funding Reduction (Army)*	1.457	-
Congressional Add: *474C – Program Increase: Restore Core Research Funding Reduction (Air Force)*	2.928	-
Congressional Add: *474D – Program Increase: Restore Core Research Funding Reduction (USUHS)*	2.553	-
Congressional Add: *495 - Peer-Reviewed Tick-Borne Disease Research*	5.000	-
Congressional Add: *496 -Trauma Clinical Research Program*	10.000	-
Congressional Add: *540A - Global HIV/AIDS Prevention (Navy)*	8.000	-
Congressional Add: *660A - Tuberous Sclerosis Complex (TSC)*	6.000	-
Congressional Add: *790A - Duchenne Muscular Dystrophy*	3.200	-
Congressional Add Subtotals for Project: 300A	1,041.539	-
Congressional Add Totals for all Projects	1,041.539	-

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*

Change Summary Explanation

FY 2016: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0603115-Medical Technology Development (+$1041.539 million).

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0603115-Medical Technology Development (-$16.531 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$16.531 million).

FY 2017: Realignment of the Medical Development Laboratory Support funding for Navy from the Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0603115-Medical Technology Development (-$38.211 million) to DHP RDT&E, PE 0606105-Medical Program-Wide Activities (+$38.211 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0603115-Medical Technology Development (-$13.599 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+$13.599 million).

FY 2017: Realignment of DHP RDTE PE 0603115 (+$8.547M) from PE 0601117 (-1.812M), 0602115 (-$3.350M), 0604110 (-$2.394M), 0605145 (-$0.633M), and 0607100 (-$0.358M) to restore Breast, GYN and Prostate Cancer Centers of Excellence.

FY 2017: Rebalance Joint Program Committees by realigning to DHP RDTE PE 0603115 (+$13.691M) from DHP RDTE PE 0604110 (-$13.403) and from DHP RDTE PE 0605145 (-0.288M).

FY 2018: Realignment from GDF DHP RDTE PE 0603115-Medical Technology Development, Project 373 Guidance for Development of the Force (-$8.000 million) to DHP RDTE PE 0603115, Project 431 Underbody Blast Testing (+$8.000 million) to fully fund the WIAMan project to the OSD CAPE cost estimate.

FY 2018: Realignment to DHP RDTE PE 0603115-Medical Technology Development, Uniformed Services University, Project 478 Applied Proteogenomics Organization Learning and Outcomes (APOLLO) Consortium (+$9.843 million) from DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development, Project 374 GDF (-$8.343 million) and DHP RDTE PE 0607110-Medical Products and Capabilities Enhancement Activities, Project 377 GDF (-$1.500 million) to support the White House-directed Cancer Moonshot initiative.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 300A / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
300A: *CSI - Congressional Special Interests*	2,839.142	1,041.539	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

In FY 2016, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2016 Congressionally-directed research is to stimulate innovative research through a competitive, peer-reviewed research program, and focused medical research at intramural and extramural research sites. Specific peer-reviewed research efforts include the following: Amyotrophic Lateral Sclerosis (ALS), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis, Cancer, Lung Cancer, Orthopedic, Spinal Cord, Vision, Traumatic Brain Injury and Psychological Health (TBI/PH), Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer Research, Joint Warfighter Medical Research, Reconstructive Transplant, Orthotics and Prosthetics Outcomes, HIV/AIDS Program, Epilepsy, Core Research Funding, Tick-borne Disease, Trauma Clinical Research, Global HIV/AIDS Prevention, Tuberous Sclerosis Complex, and Duchenne Muscular Dystrophy. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research	7.500	-
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for research in Amyotrophic Lateral Sclerosis (ALS). ALS is a degenerative neurological disorder that causes muscle weakness and atrophy throughout the body. The ALS Research Program is a broadly-competed, peer-reviewed research program with the goal to contribute to a cure for ALS by funding innovative preclinical research to develop new treatments for ALS. Two award mechanisms were released in March 2016, the Therapeutic Development Award and the Therapeutic Idea Award. Applications were received in July 2016 followed by scientific peer review in September 2016. Funding recommendations were made at programmatic review in November 2016. Nine applications were recommended for funding. Awards will be made by September 2017.		
Congressional Add: 293A - Autism Research	7.500	-
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for Autism research. The Autism Research Program seeks to improve treatment outcomes of Autism Spectrum Disorder (ASD), lead to a better understanding of ASD, and integrate basic science and clinical observations by promoting innovative research. Two award mechanisms were released in April 2016, the Clinical Trial Award and the Idea Development Award. Applications were received in September 2016 followed by scientific peer review in December 2016. Funding recommendations were made at programmatic review in February 2017. Ten applications were recommended for funding. Awards will be made by September 2017.		
Congressional Add: 296A - Bone Marrow Failure Disease Research	3.000	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for bone marrow failure diseases research. The mission of the Bone Marrow Failure Research Program is to sponsor innovative research that will advance the understanding of inherited and acquired bone marrow failure diseases, and improve the health and life of individuals living with these diseases, with the ultimate goal of prevention and/or cure. This effort has solicited research proposals focused on bone marrow failure syndromes and their long-term effects from the basic science and clinical research sectors. In FY 2016, applications were accepted through one funding opportunity, the Idea Development Award, released in February 2016. Applications were received in July 2016 followed by scientific peer review in September 2016. Funding recommendations were made at programmatic review in October 2016. Five applications were recommended for funding. Awards will be made by September 2017.		
Congressional Add: 310A - Peer-Reviewed Ovarian Cancer Research	20.000	-
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for ovarian cancer research. In striving to achieve the goal of eliminating ovarian cancer, the Ovarian Cancer Research Program (OCRP) challenges the research community to address high impact, innovative research. The FY 2016 OCRP supported innovative ideas that provide new paradigms, leverage critical resources, facilitate synergistic, multidisciplinary partnerships, and cultivate the next generation of investigators in ovarian cancer. Five award mechanisms were released in March 2016: Pilot Award, Clinical Development Award, Investigator-Initiated Research Award, Ovarian Cancer Academy Award recruiting Early-Career Investigators, and the Teal Expansion Award. Applications were received in August 2016 followed by scientific peer reviews in September and October 2016. Funding recommendations were made at the programmatic reviews in December 2016. Twenty-nine applications were recommended for funding. Awards will be made by September 2017.		
Congressional Add: 328A - Multiple Sclerosis Research	6.000	-
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for Multiple Sclerosis (MS) research. The mission of the Multiple Sclerosis Research Program (MSRP) is to support pioneering concepts and high-impact research relevant to the prevention, etiology, pathogenesis, assessment, and treatment of MS. The FY 2016 MSRP solicited applications that address MS Symptoms and Obstacles of Remyelination (nervous system repair) through three award mechanisms: Exploration Hypothesis Development Award, Investigator- Initiated Research Award, and Pilot Clinical Trial Award. Applications were received in August 2016 followed by scientific peer review in October 2016. Funding recommendations were made at		

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
programmatic review in December 2016. Ten applications were recommended for funding. Awards will be made by September 2017.		
Congressional Add: 335A - Peer-Reviewed Cancer Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for the study of cancers designated by Congress: bladder cancer, colorectal cancer, immunotherapy, kidney cancer, Listeria vaccine for cancer, liver cancer, lymphoma, melanoma and other skin cancers, mesothelioma (rare form of cancer developed from the protective lining that cover many of the internal organs of the body caused by exposure to asbestos) , neuroblastoma, pancreatic cancer, pediatric brain tumors, and stomach cancer. The goal of the Peer-Reviewed Cancer Research Program is to improve the quality of life by decreasing the impact of cancer on Service members, their families, and the American public. Four award mechanisms were released in April and June2016: Career Development Award, Idea Award with Special Focus, Translational Team Science Award, and Horizon Award. Applications were received in September 2016 followed by scientific peer review in November 2016. Funding recommendations were made at programmatic review in February 2017. Eighty-eight applications were recommended for funding. Awards will be made by September 2017.	50.000	-
Congressional Add: 336A - Peer-Reviewed Lung Cancer Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for lung cancer research. The Lung Cancer Research Program is a broadly-competed, peer-reviewed research program with the goal to eradicate deaths from lung cancer to better the health and welfare of military Service members, Veterans, their families, and the American public. Five award mechanisms were released in April and May 2016: Career Development Award, Clinical Exploration Award, Concept Award, Idea Development Award, and Investigator-Initiated Translation Research Award. Applications were received in August and September 2016 followed by scientific peer review in October and November 2016. Funding recommendations were made at programmatic review in January 2017. Twenty-eight applications were recommended for funding. Awards will be made by September 2017.	12.000	-
Congressional Add: 337A - Peer-Reviewed Orthopedic Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for orthopedic research to advance optimal treatment and rehabilitation from neuromusculoskeletal (bone, muscle, tendon, ligament, nerve, and cartilage) injuries sustained during combat or combat-related activities. The goal of the FY 2016 Peer-Reviewed Orthopaedic Research Program was to provide all Warriors affected by orthopedic injuries sustained in the defense of our Constitution the opportunity for optimal recovery and restoration of function. Four award mechanisms were released in August 2016: Clinical Trial Award, Integrated Clinical Trial Award, Clinical	30.000	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Translational Research Award, Expansion Award, and Applied Research Award. Pre-applications were received in September 2016 and applications were received in December 2016, followed by scientific peer review in February 2017. Funding recommendations will be made at programmatic review in April 2017. Awards will be made by September 2017.		
Congressional Add: 338A - Peer-Reviewed Spinal Cord Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for spinal cord injury (SCI) research. The FY 2016 Spinal Cord Injury Research Program (SCIRP) challenged the scientific community to design research that will foster new directions for and address neglected issues in the field of SCI research with particular focus on three areas: (1) pre-hospital, en route care, and early hospital management of SCI; (2) development, validation, and timing of promising interventions to address consequences of SCI and to improve recovery; and (3) identification and validation of best practices in SCI. Five award mechanisms were released in May and July 2016: Clinical Research Development Award, Clinical Trial Award, Investigator-Initiated Research Award, Qualitative Research Award, Translational Research Award. Pre-applications were received in June and September 2016, applications in September 2016, followed by scientific peer review in November 2016. Funding recommendations were made at programmatic review in January 2017. Twenty-eight applications were recommended for funding. Awards will be made by September 2017.	30.000	-
Congressional Add: 339A - Peer-Reviewed Vision Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for vision restoration research. The Peer-Reviewed Vision Research Program supported research targeting the causes, effects and treatments of eye damage, visual deficits due to traumatic brain injury (TBI) and diseases that, despite their different mechanisms of development, all have a common end result -- degeneration of the critical components of the eye and impairment or loss of vision. The results of this research are anticipated to support restoration and maintenance of visual function to ensure and sustain combat readiness and directly benefit the lives of military, Veteran and civilian populations. The FY 2016 Vision Research Program focused on 1- mitigation and treatment of damage to ocular structures and the visual system consistent to military-relevant injuries and diseases incident to military service, 2- vision restoration and regeneration, and 3- knowledge, capabilities, and equipment for early responders to diagnose and mitigate military-relevant eye injuries and diseases in austere or remote environments. Two award mechanisms for FY 2015 – FY 2016 were released in October 2015: Clinical Trial Award and Technology/Therapeutic Development Award. 78 applications were received in December 2015, followed by scientific peer review in February 2016, and programmatic review in April 2016. Twelve applications were recommended for funding. Awards will be made by September 2017.	10.000	-
Congressional Add: 352A - Traumatic Brain Injury/Psychological Health Research	97.792	-

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
FY 2016 Accomplishments: FY 2016 Accomplishments: This CSI initiative provided funds for research aimed to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and combat-related TBI on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, Veterans, family members, caregivers, and communities. Key priorities of the FY 2016 TBI and Psychological Health (PH) Research Program supported projects aligned with the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Veterans, addressed Congressional intent, enabled significant research collaborations, and complemented ongoing Department of Defense (DoD) efforts to ensure the health and readiness of our military forces by improving upon and optimizing the standards of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In addition to supporting service-requested nominations, individual Broad Agency Announcement applications, and promising ongoing studies, funding opportunities were released to solicit applications that address these priorities. The FY 2016 Clinical and Rehabilitative Medicine Complex TBI Rehabilitation Research Award program announcement (PA) was released in June 2016 to support preclinical research and clinical trials addressing TBI within specific focus areas of pain management, hearing loss/dysfunction, balance disorders, tinnitus, vision, or physical rehabilitation associated with TBI. Scientific peer review will be held in January 2017 and programmatic review in March 2017. The FY 2016 Military Operational Medicine Cognitive Resilience and Readiness Research Award PA was released in May 2016. Scientific peer review will be held in October 2016 and programmatic review in December 2016. The FY 2016 Combat Casualty Care Prolonged Field Care Research Award PA was released in May 2016 to solicit research projects on TBI therapeutics and diagnostic devices. Scientific peer review will be held in October 2016 and programmatic review in December 2016. FY 2016 awards will be made by September 2017.		
Congressional Add: 380A - Peer-Reviewed Breast Cancer Research	120.000	-
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for breast cancer research. The Breast Cancer Research Program challenged the scientific community to design research that addresses the urgency of ending breast cancer. Applications were required to address at least one of nine overarching challenges, which were focused on preventing breast cancer, identifying determinants of breast cancer initiation, risk, or susceptibility, distinguishing deadly from indolent breast cancers, conquering the problems of over-diagnosis and over-treatment, identifying what drives breast cancer growth and determining how to stop it, identifying why some breast cancers become metastatic, determining how to prevent recurrence, revolutionizing treatment regimens by replacing them with ones that are more effective and less toxic, and eliminating the mortality associated with metastatic breast cancer. Six award mechanisms were released in March, July, and August 2016: Breakthrough Award Levels 1 and 2, Breakthrough Award Levels 3 and 4,		

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Distinguished Investigator Award, Era of Hope Scholar Award, Innovator Award, and Breakthrough Fellowship Award. Application submission deadlines were in May, August, November, and December 2016, scientific peer reviews were in July and October 2016 and January 2017, and programmatic reviews in September and November 2016 and January and March 2017. Ninety applications were recommended for funding. Awards will be made by 30 September 2017.		
Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for prostate cancer research. The vision for the FY 2016 Prostate Cancer Research Program (PCRP) was to conquer prostate cancer by funding research to eliminate death from prostate cancer and enhance the well-being of men experiencing the impact of the disease. To address the most critical current needs in prostate cancer research and clinical care, the PCRP solicited research applications addressing four overarching challenges: 1- distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer, 2- develop strategies to prevent progression to lethal prostate cancer, 3- develop effective treatments and address mechanisms of resistance for men with high risk or metastatic prostate cancer, and 4- develop strategies to optimize the physical and mental health of men with prostate cancer. In addition, research projects are being solicited in the areas of biomarker (biological indicator of health outcomes and disease) development, genetics, imaging, mechanisms of resistance, survivorship and palliative care, therapy, and tumor and microenvironment biology. Six award mechanisms were released in May and June 2016: Clinical Consortium Research Site Award, Early Investigator Research Award, Health Disparity Research Award, Idea Development Award, Impact Award, and Physician Research Award. Applications were received in July, August, and October 2016, followed by scientific peer reviews in September, October, and November 2016. Funding recommendations were made at programmatic reviews in December 2016 and January 2017. One hundred seven applications were recommended for funding. Awards will be made by September 2017.	80.000	-
Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for Gulf War Illness research. The vision for the FY 2016 Gulf War Illness Research Program was improving the health and lives of Veterans who have Gulf War Illness by funding research to identify effective treatments, improve clinical definition and diagnosis, and to better understand the underlying biology and symptoms of Gulf War Illness. Five award mechanisms were released in May 2016: Clinical Partnership Award, Treatment Evaluation Award, Investigator-Initiated Focused Research Award, Gulf War Illness Epidemiology Research Award, and New Investigator Award. Applications were received in October 2016 followed by scientific peer review in December	20.000	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
2016. Funding recommendations were made at programmatic review in February 2017. Twenty-seven awards were recommended for funding. Awards will be made by September 2017.		
Congressional Add: 396A - Research in Alcohol and Substance Use Disorders	4.000	-
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for alcohol and substance use disorders (ASUD) research. The goal of the FY 2016 Alcohol and Substance Abuse Disorders Research Program was to identify and develop new medications to improve treatment outcomes for ASUD, especially related to traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD). On 30 September 2015, Research Triangle Institute (RTI) was awarded a $10.8M 5-year award from the FY14 Alcohol and Substance Abuse Research Program (ASARP) Consortia Award Program Announcement. RTI leads the "Pharmacotherapies for Alcohol and Substance Abuse" (PASA) consortium, in collaboration with Baylor College of Medicine and Uniformed Services University of Health Sciences. The consortium has three aims in developing pharmacotherapies for ASUDs, particularly in the context of the reciprocal relationship between ASUD versus stress and anxiety as manifested in PTSD/TBI. The three broad aims are: 1- Discover novel medications and combination medications for ASUDs and PTSD/TBI, 2- Develop these medications through a rational proof of concept pipeline model, and 3- Conduct Phase II preliminary efficacy trials of potential medication combinations in optimal target populations and explore functional genetic polymorphisms for matching patients to these medications. FY 2016 funds were added to this award in June 2016.		
Congressional Add: 400A - Peer-Reviewed Medical Research	278.700	-
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for military-relevant research in Congressionally directed topic areas toward the goal of improving the health and well-being of all military Service members, Veterans, and beneficiaries. The 39 Congressionally-directed topics for FY 2016 were: Acute Lung Injury, Antimicrobial Resistance, Chronic Migraine and Post-traumatic Headache, Congenital Heart Disease, Constrictive Bronchiolitis, Diabetes, Dystonia, Emerging Infectious Diseases, Focal Segmental Glomerulosclerosis, Fragile X Syndrome, Hepatitis B, Hereditary Angioedema, Hydrocephalus, Inflammatory Bowel Disease, Influenza, Integrative Medicine, Interstitial Cystitis, Lupus, Malaria, Metals Toxicology, Mitochondrial Disease, Nanomaterials for Bone Regeneration, Non-Opioid Pain Management, Pancreatitis, Pathogen-inactivated Dried Plasma, Polycystic Kidney Disease, Post-Traumatic Osteoarthritis, Psychotropic Medications, Pulmonary Fibrosis, Respiratory Health, Rett Syndrome, Rheumatoid Arthritis, Scleroderma, Sleep Disorders, Tinnitus, Tuberculosis, Vaccine Development for Infectious Disease, Vascular Malformations, and Women's Heart Disease. Five award mechanisms were offered in FY 2016: Clinical Trial Award, Discovery Award, Focused Program Award, Investigator- Initiated Research Award, and Technology/ Therapeutic Development Award. For the Discovery Award, application receipt occurred in July 2016, scientific		

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
peer review was conducted in September 2016, and funding recommendations were made during programmatic review in November 2016. For the remaining mechanisms, application receipt occurred in October 2016, peer review was conducted in December 2016, and funding recommendations were made during programmatic review in February 2017. One hundred forty-six awards were recommended for funding. Awards will be made by September 2017.		
Congressional Add: 417A - Peer-Reviewed Alzheimer Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for Alzheimer's disease research. The FY 2016 Peer-Reviewed Alzheimer's Research Program (PRARP) sought to: 1- address the long-term consequences of traumatic brain injury (TBI) as they pertain to Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD); and 2- reduce the burden on AD/ADRD-affected individuals and caregivers, especially in the military and Veteran communities. Four award mechanisms were released in July 2016: Convergence Science Research Award, Quality of Life Research Award, Translational Research Partnership Award, and Epidemiology of Military Risk Factors Research Award. Pre-applications were received in August 2016, applications in November 2016, followed by peer review in January 2017. Funding recommendations were made at programmatic review in April 2017. Fifteen applications were recommended for funding. Awards will be made by September 2017.	15.000	-
Congressional Add: 439A - Joint Warfighter Medical Research ***FY 2016 Accomplishments:*** The FY 2016 Joint Warfighter Medical Research Program (JWMRP) aimed to provide continuing support for promising projects that were previously funded by Congressional Special Interest (CSI) initiatives. The focus was to augment and accelerate high priority DoD and Service medical requirements that are close to achieving their objectives and yield a benefit to military medicine. The FY 2016 JWMRP supported military medical research in medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, , and clinical and rehabilitative medicine. Through an iterative process of recommendations, prior year CSI-funded projects were nominated for consideration by the Services, Joint Program Committees, and Execution Management Agencies. Those projects deemed by the Service representatives and Joint Program Committees to have the highest priority to fill critical research or materiel gaps and those projects close to developing a product were invited to submit a pre-application. All pre-applications were reviewed and full application invites were sent in February 2016. The external scientific peer review occurred in May 2016 with the programmatic review in June 2016. Twenty-five projects were recommended for funding. Awards will be made by September 2017.	30.000	-
Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research	12.000	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for reconstructive transplantation research. The FY 2016 Reconstructive Transplant Research Program (RTRP) focused on research in reconstructive transplantation for the refinement of approaches for hand, face, and other vascularized composite tissue allografts, as well as the transplants of skin, muscle, tendon, nerves, bone, and blood vessels. Four award mechanisms were released in August 2016: Concept Award, Investigator-Initiated Research Award, Technology Development Award, and Qualitative Research Award. Letters of intent for the Concept Award were received in November 2016, while pre-applications for the other three award mechanisms were received in September 2016. Applications for all award mechanisms were received in December 2016, followed by scientific peer review in February 2017. At programmatic review in April 2017, Fifteen applications were recommended for funding. Awards will be made by September 2017.		
Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for orthotics and prosthetics outcomes research. The goal of the FY 2016 Orthotics and Prosthetics Outcomes Research Program was to advance research toward more effective prosthetic and orthotic devices, treatment, rehabilitation, and the prevention of negative secondary health effects for military personnel, Veterans, and persons with injured limb function. Two award mechanisms were released in July 2016: Orthotics Outcomes Research Award, and Prosthetics Outcomes Research Award. Pre-applications were received in August 2016 and applications in November 2016. Scientific peer review was held in January 2017, and programmatic review occurred in March 2017. Thirteen applications were recommended for funding. Awards will be made by September 2017.	10.000	-
Congressional Add: 456A - HIV/AIDS Program ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative complemented the funding for the HIV/AIDS research program. Several potential vaccine candidates were down-selected for further testing in human volunteers to study their ability to provoke an immune response that can protect against HIV either as a single vaccine or combination of various subtypes.	12.900	-
Congressional Add: 459A - Peer-Reviewed Epilepsy Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for traumatic brain injury (TBI)-related epilepsy research. The FY 2016 Peer Reviewed Epilepsy Research Program supported studies to examine the interconnection between TBI and epilepsy in four scientific focus areas: 1- epidemiology, 2- markers and mechanisms of post traumatic epilepsy, 3- models of post-traumatic epilepsy, and 4- research into psychogenic (non-epileptic) seizures. One award mechanism, the Idea Development Award, was released in July 2016. Pre-applications were received in August 2016, and applications will be received in November	7.500	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
2016. Peer review was held in January 2017, and programmatic review in April 2017. Six applications were recommended for funding. Awards will be made by September 2017.		
Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2016 Accomplishments:*** This CSI initiative was directed toward FY 2016 Defense Health Program (DHP) core research initiatives in PE 0603115. Funds supported medical technology development efforts in medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, and clinical and rehabilitative medicine (Project 373A).	138.509	-
Congressional Add: 474A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2016 Accomplishments:*** FY 2016 DHP CSI was directed toward the restoral of Army research initiatives in PE 0603115. Funds supported research for the Cardiac Health CoE (381A), Military HIV Research (448A), and Deployed Warfighter Protection (830A).	1.457	-
Congressional Add: 474C – Program Increase: Restore Core Research Funding Reduction (Air Force) ***FY 2016 Accomplishments:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported Air Force research in Force Health Protection (307B).	2.928	-
Congressional Add: 474D – Program Increase: Restore Core Research Funding Reduction (USUHS) ***FY 2016 Accomplishments:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported University research in Regenerative Medicine (Project 309A), Prostate Cancer CoE (383A), Breast Cancer CoE (378B), Gynecological CoE (379B) and Pain CoE (382B).	2.553	-
Congressional Add: 495 - Peer-Reviewed Tick-Borne Disease Research ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for tick-borne diseases research. The FY 2016 Peer Reviewed Tick-Borne Disease Research Program's mission was to support research focused on understanding the pathogenesis of Lyme disease and other tick-borne illness and on delivering innovative solutions to prevent and better diagnose and treat their manifestations. Two funding opportunities were released in June 2016: Idea Award and Investigator-Initiated Research Award. Pre-applications were received in August 2016 and applications were received in November 2016. Scientific peer review was held in January 2017, and funding recommendations were made at programmatic review in March 2017. Six applications were recommended for funding. Awards will be made by September 2017.	5.000	-
Congressional Add: 496 -Trauma Clinical Research Program	10.000	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for advancing trauma clinical research. The DoD is creating a coordinated, multi-institution, clinical research network of civilian and military trauma centers to address the military relevant priorities and gaps in trauma care. The Combat Casualty Care Research Program of the US Army Medical Research and Materiel Command will include this CSI funding and core Defense Health Program Research, Development, Test and Evaluation program funding for future planning and execution of the Linking Investigations in Trauma and Emergency Services (LITES) trauma research network Indefinite Deliverable Indefinite Quantity (IDIQ) Contract. The LITES network shall create a standing research consortium of US trauma systems and centers with the capability to conduct prospective, multicenter, injury care and outcomes research of relevance to the Department of Defense. The pre-solicitation announcement for the LITES network Request for Proposals (RFP) was released in May 2016. The RFP was released in June 2016. The Source Selection Evaluation Board evaluation and award was completed in September 2016. A new task order to execute remaining FY16 funds will be negotiated and executed by September 2017.		
Congressional Add: 540A - Global HIV/AIDS Prevention (Navy)	8.000	-
FY 2016 Accomplishments: This Congressional Special Interest project supports Global HIV/AIDS Prevention research. Program emphasis is placed on (1) assisting partner militaries to build a national research infrastructure by funding large, multidisciplinary program projects focused on HIV detection; (2) encouraging innovative approaches to research by funding new ideas and technology with or without supporting preliminary data; and (3) recruiting new, independent scientists and practitioners in research, as well as more senior investigators new to the research field. The strategy for the FY 2016 Congressionally directed research identified above is to stimulate innovative research through a competitive, peer reviewed research program, as well as focused medical research at intramural and extramural research sites. Specific research efforts include HIV/AIDS. The HIV/AIDS Prevention program conducts on-site visits to determine eligible areas for technical assistance and resource support. The program provides support to defense forces in the following areas: (1) HIV prevention, which includes training of medical personnel and peer educators, education of military members, provision of condoms and other prevention materials, provision of		

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
educational materials such as brochures, posters, and booklets (2) care for HIV-infected individuals and their families to include provision of electronic medical record programs, medications to treat HIV-related issues, physician education, and clinic infrastructure support, (3) treatment services including provision of laboratory services such as HIV test kits, and other laboratory equipment, and (4) Strategic Information including systems to collect information on the effectiveness of HIV treatment and prevention programs and generate databases of such information to guide treatment and prevention programs. Annual program data collection is currently being conducted in the 20 countries that are receiving funding from this CSI. Accomplishments for FY 2016 will be reported after the collection is complete. Because of the CSI annual structure, out-year funding is not programmed.		
Congressional Add: 660A - Tuberous Sclerosis Complex (TSC) ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for Tuberous Sclerosis Complex (TSC) research. The FY 2016 Peer Reviewed Tuberous Sclerosis Complex Research Program (TSCRP) sought to support innovative research to improve the lives of individuals with TSC through understanding the pathogenesis and manifestations of TSC and developing improved diagnostic and treatment approaches. Five award mechanisms were released in May 2016: Idea Development Award, Exploration-Hypothesis Development Award, Synergistic Idea Development Award, Postdoctoral Development Award, and Pilot Clinical Trial Award. Applications were received in July 2016, followed by scientific peer review in September 2016. Funding recommendations were made at programmatic review in November 2016. Ten applications were recommended for funding. Awards will be made by September 2017.	6.000	-
Congressional Add: 790A - Duchenne Muscular Dystrophy ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative provided funds for Duchenne Muscular Dystrophy (DMD) research. DMD is caused by gene mutations in skeletal muscle proteins, and affects approximately 1 in 3,600 boys causing muscle degeneration and eventual death. The goal of the FY 2016 Duchenne Muscular Dystrophy Research Program was to preserve and improve the function and quality of life, and to extend the lifespan of all individuals with Duchenne by supporting research for the discovery, development, and clinical testing of novel therapeutics. Two award mechanisms were released in May 2016: Career Development Award and Investigator-Initiated Research Award. Applications were received in October	3.200	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
2016 with scientific peer review conducted in January 2017 followed by programmatic review in March 2017. Four applications were recommended for funding. Awards will be made by September 2017.		
Congressional Adds Subtotals	1,041.539	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Research proposals will be solicited by program announcements resulting in grants, contracts, or other transactions.

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 238C / *Enroute Care Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
238C: *Enroute Care Research & Development (Budgeted) (AF)*	11.633	1.340	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into products. The sub-project areas include: Impact of Transport on patients and providers (physiological effects of transport factors on patients and crew and impact of transport times on En-Route Trauma and Resuscitative Care), patient safety (includes En-Route data analytics and the optimization of patient care), medical technologies which includes technology advances and clinical assessment at altitude, and research to support En-Route education and training with simulation.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Enroute Care Research & Development (Budgeted) (AF)	1.340	0.000	0.000

Description: This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into products. The sub-project areas include: Impact of Transport on patients and providers (physiological effects of transport factors on patients and crew and impact of transport times on En-Route Trauma and Resuscitative Care), patient safety (includes En-Route data analytics and the optimization of patient care), medical technologies which includes technology advances and clinical assessment at altitude, and research to support En-Route education and training with simulation.

FY 2016 Accomplishments:

Evaluate the benefit of cabin altitude restriction, the incidence of gas emboli through the circuit during transport, and the benefit of adding additional venous drainage during periods of hypoxemia. Evaluate current practices regarding transportation of critically ill patients without traumatic injuries and incorporate results in the DoD critical care training curriculum. Retrospectively describe traumatic cardiopulmonary arrest (TCPA) patients in the battlefield and determine if they meet the current published guidelines for resuscitation of traumatic cardiac arrest. Identify independent predictors that are associated with increased survival among TCPA patients in a combat theater. Describe mechanical ventilation methods during the transport of critically injured and ill patients by CCATT to validate existing CCATT clinical practice guidelines. Conduct an Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) Psychiatric Medical Evacuation (MEDEVAC) analysis of psychological assessment, diagnostic categorization, risk and protective factors, aeromedical classification, aeromedical transportation safety and disposition of military personnel aeromedically evacuated from OEF/OIF for psychiatric reasons to facilitate recommendations to improve patient, aircrew and aircraft safety. Develop algorithm based on sensitive and specific markers of renal damage to aid in predicting the efficacy/safety

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 238C / *Enroute Care Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
of further volume resuscitation and to predict pre-hospital prognosis in warfighters. Evaluate the combat-feasible Extracorporeal Life Support (ECLS) approach to managing complex injuries which occur in combat such as massive trauma with exsanguination, trauma pneumonectomy, retro-hepatic IVC injuries, and severe traumatic brain injury (sTBI). Record the indications for ECLS initiation and transport across the DoD to implement a robust electronic alert system for identifying critically ill patients in a deployed environment. Continue research to identify the effects of altitude on various injury states and investigate biomarkers as predictors of acute lung injury, acute kidney injury, and traumatic brain injury prior to AE. Begin simulation research program: validate skill / outcome measures, develop simulation improvements / technologies to achieve those outcomes, understand perishability of skills. Continue medical device clinical validation at altitude work. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Plans:*** Continue as planned in FY17.			
Accomplishments/Planned Programs Subtotals	1.340	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, PE 0807714HP: *Other Consolidated Health Support*	13.844	14.259	14.655	-	14.655	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 238D / *Core Enroute Care R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
238D: *Core Enroute Care R&D - Clinical Translational Focus (AF)*	0.000	0.997	2.045	2.240	-	2.240	3.416	4.045	4.124	4.209	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on seriously injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into transitionable products. The sub-project areas include: Physiological Effects of Aeromedical Evacuation on patients and crew which includes the optimization of provider performance and patient care, impact of transport times on En-Route Trauma and Resuscitative Care, and En-Route Patient Safety which includes technology advances and assessment. Because patients experience multiple handoffs between teams of caregivers during transport between austere environments and definitive care, efforts in the En-Route Patient Safety sub-project area examine human factors considerations in order to develop new and enhance existing methods to mitigate risk in all En-Route care environments.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Enroute Care R&D - Clinical Translational Focus (AF)	0.997	2.045	2.240

Description: This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on seriously injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into transitionable products. The sub-project areas include: Physiological Effects of Aeromedical Evacuation on patients and crew which includes the optimization of provider performance and patient care, impact of transport times on En-Route Trauma and Resuscitative Care, and En-Route Patient Safety which includes technology advances and assessment. Because patients experience multiple handoffs between teams of caregivers during transport between austere environments and definitive care, efforts in the En-Route Patient Safety sub-project area examine human factors considerations in order to develop new and enhance existing methods to mitigate risk in all En-Route care environments.

FY 2016 Accomplishments:

Analyze final results of swine study investigating post AE effects on coagulation and inflammation, which will lead to a knowledge platform to develop guidelines for evacuation strategies during transport of combat casualties. Pursuant system build and demonstration of the closed loop ventilation and oxygen delivery system, the data from the pre-hospital use of capnometry and the ventilator registry will be used to define the requirements of a system to perform closed loop ventilation. Continue pursuing the AFMS strategic goal A1 to “Transform the En-route Care System” based on war fighter identified gaps and validated requirements. Begin and/or continue work that will improve mission effectiveness in the A2AD environment such as closed loop technologies and enabling capabilities leading to autonomous patient transport.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 238D / *Core Enroute Care R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
FY16 program cost is $2.25M; UFR = $1.253M ***FY 2017 Plans:*** Continue pursuing the AFMS strategic goal A1 to "Transform the En-Route Care System" based on war fighter identified gaps and validated requirements. Begin and/or continue work that will improve mission effectiveness in the A2AD environment such as closed loop technologies and enabling capabilities leading to autonomous patient transport. Continue to identify independent predictors that are associated with increased survival among patients in a combat theater and update clinical practice and training guidelines to support resulting best practices. Establish database for medical evacuation treatment indicators with care and resolution outcomes. ***FY 2018 Plans:*** Continue as planned in FY17.			
Accomplishments/Planned Programs Subtotals	0.997	2.045	2.240

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 238E / *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
238E: *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.997	2.045	2.239	-	2.239	3.417	4.043	4.125	4.209	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to advance aeromedical evacuation (AE), Critical Care Air Transport Team (CCATT), and Tactical Critical Care Evacuation Team (TCCET) capabilities through the research and development of rapid, more efficient, and safer patient transport from the pre-staging for strategic or intra-theater air evacuation to definitive care, and to understand the effects of transport on injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into translatable practice and technology products. The sub-project areas include: Impact of Transport on patients and crew which includes the optimization of provider performance and patient care, En-Route Medical Technologies which includes technology advances and assessment, and En-Route Patient Safety which includes efforts to ensure the safe transport of patients through the AE system.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)	0.997	2.045	2.239

Description: This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into products. The sub-project areas include: Impact of Transport on patients and providers (physiological effects of transport factors on patients and crew and impact of transport times on En-Route trauma and resuscitative care), patient safety (includes En-Route data analytics and the optimization of patient care), medical technologies which includes technology advances and clinical assessment at altitude, and research to support En-Route education and training with simulation.

FY 2016 Accomplishments:

Continue development of the En-Route care retrospective research database. Continue research to identify the effects of altitude on various injury states and investigate biomarkers as predictors of acute lung injury, acute kidney injury, and traumatic brain injury prior to AE. Begin simulation research program: validate skill / outcome measures, develop simulation improvements / technologies to achieve those outcomes, understand perishability of skills. Continue medical device clinical validation at altitude work. Continue closed loop medical interventions research and development. Begin to characterize vibration on transport platforms. Begin to investigate medication efficacy at altitude. Continue investigating new research and development requirements based on results of prior studies and warfighter gap analyses. Begin development of an animal-free, human-free tool for testing efficacy and safety of medications and biochemical pain mitigation strategies during aeromedical evacuation flights.

FY 2017 Plans:

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 238E / *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Investigate operational questions through use of the En-Route care retrospective research database. Continue research to identify the effects of altitude on various injury states and investigate biomarkers as predictors of acute lung injury, acute kidney injury, and traumatic brain injury prior to AE. Continue simulation research program: validate skill / outcome measures, develop simulation improvements / technologies to achieve those outcomes, understand perishability of skills. Continue medical device clinical validation at altitude work. Continue closed loop medical interventions research and development. Continue to characterize vibration on transport platforms. Continue initial investigation of medication efficacy at altitude. Continue investigating new research and development requirements based on results of prior studies and warfighter gap analyses. ***FY 2018 Plans:*** Continue with developing research objectives and end states focused in the five AE research Core Capability Areas (CCAs): Clinical En-Route Care, En-Route Education, Training and Simulation, En-Route Medical Technologies, Impact of Transport, and Patient Safety. A description of the CCA's follows: The focus of En-route Clinical Care is to advance patient care during transport, staging, and validation of the sick and wounded with the goal of improved short and long term outcomes. Clinical Care research will be translational to improve or create clinical practice guidelines, tactics, and techniques to ensure patients receive the same level of care in transport environments as expected in state-of-the art facilities. Education, training and simulation research will focus on providing solutions to training gaps in the AE enterprise. Research is required to study education and training methodologies to maximize efficiencies, effectiveness, and cost economics to optimize patient outcomes. En-Route medical technologies research will focus on developing or modifying and testing equipment to ensure care-givers provide state of the art care during transport. Impact of transport provides knowledge by conducting research to investigate impact of AE on injury and disease, pathophysiology and management. The focus is to understand the currency of knowledge of stressors of flight and characterize baseline factors (e.g. flight duration, vibration, lighting, noise, altitude) as required to facilitate investigation to mitigate negative impact of transport. Patient safety supports Trusted Care through continuous process improvement in the development of evidence based Clinical Practice Guidelines (CPG), standardized work processes and training, and intelligent database support modules to reduce variability, prevent harm and improve care and outcomes across the AE continuum of care.			
Accomplishments/Planned Programs Subtotals	0.997	2.045	2.239

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 238E / *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 243A / *Medical Development (Lab Support) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
243A: *Medical Development (Lab Support) (Navy)*	128.420	35.878	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

For the Navy Bureau of Medicine and Surgery, this program element (PE) includes costs related to laboratory management and support salaries of government employees that are not paid from science/research competitively awarded funding. The Outside Continental U.S. (OCONUS) laboratories conduct focused medical research on vaccine development for Malaria, Diarrhea Diseases, and Dengue Fever. In addition to entomology, the labs focus on HIV studies, surveillance and outbreak response under the Global Emerging Infections Surveillance (GEIS) program, and risk assessment studies on a number of other infectious diseases that are present in the geographical regions where the laboratories are located. The CONUS laboratories conduct research on Military Operational Medicine, Combat Casualty Care, Diving and Submarine Medicine, Infectious Diseases, Environmental and Occupational Health, Directed Energy, and Aviation Medicine and Human Performance.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Medical Development (Lab Support) (Navy)	35.878	0.000	-
Description: Funding in this project code covers operating and miscellaneous support costs at RDT&E laboratories, including facility, equipment and civilian personnel costs that are not directly chargeable to RDT&E projects. Excluded costs include military manpower and related costs, non-RDT&E base operating costs, and military construction costs, which are included in other appropriate programs.			
FY 2016 Accomplishments: Provided operating support for eight medical RDT&E labs across 15 product lines to develop products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter, and enable the labs to meet or exceed science performance metric objectives.			
FY 2017 Plans: Funding for Medical Development (Lab Support) (Navy) was realigned to Program Element (PE) 0606105 - Medical Program-Wide Activities.			
Accomplishments/Planned Programs Subtotals	35.878	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 243A / *Medical Development (Lab Support) (Navy)*

D. Acquisition Strategy

N/A

E. Performance Metrics

Metrics include timely and proportionate distribution of funds to labs and product lines to optimize resource utilization in the development and evaluation of products that protect, treat, rehabilitate and enhance the performance of the Warfighter.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 247A / *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
247A: *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	0.200	2.060	2.064	1.548	-	1.548	0.000	0.000	0.000	0.000	0.000	5.872

A. Mission Description and Budget Item Justification

This project seeks to demonstrate that malaria can be eliminated in a specific geographically defined area of endemicity through a comprehensive multi-disciplined approach including enhanced surveillance, research to maximize the impact of intervention strategies, and quality improvement of current tools for malaria elimination. The demonstration will focus on Vietnam where multi-drug resistant malaria is prevalent and as such represents a significant threat to US personnel. Additionally, the Vietnamese military and Ministry of Health have a high level of interest in malaria control and will collaborate in the malaria elimination demonstration project, significantly improving the chances of success of this project. Successful completion of this project could significantly enhance force health protection and global engagement by providing a vetted approach to malaria control in the Southeast Asia region where multi-drug resistant malaria is a major infectious disease threat. This project supports (both directly and indirectly in a priority country - Vietnam) Global Health Security Agenda priorities: Combat Antibiotic Resistance Bacteria (CARB); Prevent Avoidable Epidemics; Detect Threats Early; and Respond Rapidly and Effectively to biological threats of international concern.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Elimination of Malaria in Southeast Asia (CARB) (Navy)	2.060	2.064	1.548

Description: This project seeks to demonstrate that malaria can be eliminated in a specific geographically defined area of endemicity through a comprehensive multi-disciplined approach including enhanced surveillance, operations research to maximize the impact of intervention strategies, and quality improvement of current tools for malaria elimination. The demonstration will focus on Vietnam where multi-drug resistant malaria is prevalent and as such represents a significant threat to US personnel. Additionally the Vietnamese military and Ministry of Health have a high level of interest in malaria control and will collaborate in the malaria elimination demonstration project significantly improving the chances of success of this project.

FY 2016 Accomplishments:

Enhanced surveillance activities with the Ministry of Health were continued at sites in central Vietnam and on the Laos border. This project has identified risk factors among forest goers, similar to US military personnel in terms of age, health and activity, associated with acquiring malaria. Preliminary data from 2015 and 2016 presented at the American Society of Tropical Medicine and Hygiene (Nov 2016); this information will inform future studies on malaria interventions. To continue work in Vietnam with the Ministry of Health a 2-year work plan was approved in July 2016.

Continued recruitment of Vietnam-Australia-US military collaborative study to characterize drug resistance in central Vietnam. Preliminary data, indicating no drug resistance present at study site, presented at the USPACOM Asia Pacific Military Health Exchange in Kuantan, Malaysia (Aug 2016). Cross sectional study protocol approved by Vietnam Ministry of Defense; this project will start in Q1 FY17 targeting people served by military clinics in Gai Lia Province, a remote area on the Cambodia border.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 247A / *Elimination of Malaria in Southeast Asia (CARB) (Navy)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Per the US Consulate in Ho Chi Min City this area is not routinely open to US projects; this study site, selected by the Vietnam military, represents an important area for mobile populations (similar to US military in terms of age, health and activity) moving through malaria endemic areas and a tangible measure of the trust developed with the Vietnam military due to malaria project collaborations. ***FY 2017 Plans:*** Continuing FY16 work, FY17 funding will support the modeling of collected malaria surveillance and intervention data to measure the impact of previous interventions in Vietnam. The Ministry of Health has agreed in principal to provide malaria data from 2010-2015 to study the impact of environmental, climatic and control/elimination factors on malaria burden. This effort will be enhanced by continuation of ongoing surveillance efforts with the Ministry of Health with expanded collection of blood samples to evaluate current malaria infection by microscopic and PCR detection of malaria parasites and historic malaria exposure by antibody testing. These activities will improve the understanding of malaria parasite diversity and the distribution of drug resistance along the Vietnam-Cambodia-Laos border region. The focus of efforts with the Ministry of Health will be studying malaria transmission within the country and transport of malaria parasites along the Laos-Cambodia-Vietnam border, a new project will be initiated to detect malaria infection in people returning from working in Africa. This project will provide insight into the transport of which may impact malaria transmission patterns in Vietnam. In FY17 efforts with the Ministry of Defense will focus on completing the cross-sectional study approved in FY16. This study will be conducted in Gai Lia Province on the Cambodia border and provide information on subclinical malaria infection. Subclinical infections are not captured in routine surveillance activities; this gap impacts Vietnam's malaria elimination program and US force health protection strategy as these cases are part of the malaria transmission cycle. Clinical studies on malaria drug resistance will continue in FY17; the study in Ninh Thuan Province will conclude recruitment in Q1 FY17 with sample/data analysis expected to be completed in Q3 FY17. The Ministry of Defense is reviewing a new clinical study for malaria drug resistance in Dak Nong Province on the Cambodia border, this study is expected to begin in Q3 FY17 and continue for two years. ***FY 2018 Plans:*** Building on partnerships with the Ministries of Health and Defense surveillance activities will continue in border areas with known malaria drug resistance. Surveillance efforts will be augmented by pilot testing intervention products and packages that could be utilized by the Vietnam National Malaria Control Program and the US DoD to inform malaria prevention and control programs. Surveillance and malaria control/elimination products and strategies will be evaluated using approaches harmonized with the World Health Organization and US DoD Defense Malaria Assistance Program. Study results and recommendations will be reported in refereed professional journals and policy recommendations submitted to the Vietnamese and US Governments. The project will come to an end in FY18/19- therefore, no funding is budgeted in the years following.			
Accomplishments/Planned Programs Subtotals	2.060	2.064	1.548

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 247A / *Elimination of Malaria in Southeast Asia (CARB) (Navy)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Successful execution of this project will be measured by significant reduction of malaria parasite incidence and prevalence in the geographic area of study. Study results and recommendations will be reported in refereed professional journals and policy recommendations submitted to the Vietnamese and US Governments.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 247B / *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
247B: *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	0.425	1.040	1.135	1.238	-	1.238	0.000	0.000	0.000	0.000	0.000	3.838

A. Mission Description and Budget Item Justification

This project seeks to demonstrate that the impact of sepsis (severe infections) in Egypt can be mitigated through the Austere Environment Consortium for Enhanced Sepsis Outcomes (ACESO) approach of discovering common, host-based pathogenic pathways for improved recognition and management of sepsis and point of care (POC) diagnostic and prognostic biomarker panels. Sepsis is the common path to end-organ damage and death for a large proportion of globally-important infectious diseases. This project will improve the understanding of disease pathogenesis and antimicrobial resistance mechanisms through network and biomarker analysis thus offering unique opportunities for improving sepsis diagnosis and management. Through systematic biology, it will develop insight into the disease pathogenesis of sepsis, and host factors which predict susceptibility, and sepsis severity provides opportunity for targeted interventions to forestall morbidity and mortality. Furthermore, enhanced knowledge of emerging antimicrobial resistance in strategic regions informs ongoing surveillance and mitigation efforts of critical importance to deployed forces. Successful completion of this project will provide reliable antimicrobial resistance data for forces deploying to Egypt and the region and also document improved methods for the treatment and management of sepsis. ACESO is an international consortium of sepsis researchers led by NMRC that has established a network of sepsis research sites in SE Asia and Sub-Saharan Africa to improve clinical outcomes and advance our understanding of pathogenesis, biomarkers of sepsis and antimicrobial resistance trends. The proximity of NAMRU-3 to the largest infectious disease hospital in Egypt (Abbassia Fever Hospital) affords an unparalleled opportunity for ACESO expansion and will provide critical severe infection and antimicrobial resistance data from the important North African Theater. This project supports (both directly and indirectly) Global Health Security Agenda priorities: Combat Antibiotic Resistance Bacteria (CARB); Prevent Avoidable Epidemics; Detect Threats Early; and Respond Rapidly and Effectively to biological threats of international concern

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)	1.040	1.135	1.238
Description: This project seeks to demonstrate that the impact of sepsis from resistant and other high risk organisms in Egypt can be mitigated through the Austere Environment Consortium for Enhanced Sepsis Outcomes (ACESO) approach of discovering common, host-based pathogenic pathways for improved recognition and management of sepsis. This project will improve understanding of pathogenesis and antimicrobial resistance mechanisms through network and biomarker analysis to offer unique opportunities for improving sepsis diagnosis and management. Most specifically, ACESO will execute biomarker discovery identifying diagnostic and prognostic biomarker panels which may improve sepsis management in all environments including resourced and austere			
FY 2016 Accomplishments: FY16 efforts supported the continuation of the observational study of patients with sepsis in Egypt admitted to the Abbassia Fever Hospital, adjacent to NAMRU-3, Cairo. The goals of this study are to 1) identify diagnostic and prognostic markers, 2) investigate			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 247B / *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
common pathogenic pathways, 3) describe the spectrum of pathogens causing sepsis, 4) describe the treatment strategies currently in use, and 5) assess the long-term sequelae. Adult patients with suspected infection and evidence of systemic inflammation were considered for enrollment. Laboratory testing augmented the testing routinely performed at the hospital microbiology laboratory, and included diagnostic tests (e.g. blood cultures, malaria smears, HIV tests, and serology), molecular diagnostics (e.g. microarray analysis, multiplex polymerase chain reactions (PCR), and sequencing), and assays measuring the host-response (biomarker assays and host transcriptome arrays). Sophisticated analytic and statistical approaches were applied to the complex data set to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways. ***FY 2017 Plans:*** FY17 funding will support the continuation of the observational study at the Abbassia Fever Hospital and the sophisticated analytic and statistical approaches will be applied to this complex data set to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways. ***FY 2018 Plans:*** FY18 funding will support the translation of observational studies at the Abbassia Fever Hospital to develop sophisticated analytical and statistical approaches to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways. Additionally, antimicrobial resistance patterns determined from the observational studies will be combined with prognostic markers for sepsis and common pathogenic pathway data to achieve improved patient outcomes. The project will come to an end in FY18/19- therefore no funding is budgeted in the years following.			
Accomplishments/Planned Programs Subtotals	1.040	1.135	1.238

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Successful execution of this project will be measured by significant reduction in the mortality rate from sepsis, reduced hospitalization days, and by the number and impact factor of publications in refereed professional journals.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284B / *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	8.545	1.700	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to Operational and Environmental Challenges to Performance.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)	1.700	0.000	0.000
Description: This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to Operational and Environmental Challenges to Performance.			
FY 2016 Accomplishments: Expand evaluations of promising fatigue and cognitive management modalities. Conclude efforts identifying the effects of combining over-the-counter stimulants with Modafinil, which may stimulate the need for further research. Apply results from high altitude and hypoxia studies to refine this line of research to define what is a “safe” altitude and potentially spur operational changes. Implement plans to pursue human systems integration studies, focusing on identified gaps. Mature a comprehensive program working to define and mitigate the extreme physiological demands of higher altitudes to include decompression sickness and hypoxia. Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions magnify each other. Advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284B / *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Concluded efforts identifying and validating the effects of combining over-the-counter stimulants with Modafinil on cognitive performance, final research products delivered. ***FY 2017 Plans:*** No funding programmed. ***FY 2018 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	1.700	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

SEE OTHER PROGRAM FUNDING SUMMARY FOR PROJECT CODE 238C WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 284C / *Core Human Performance R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
284C: *Core Human Performance R&D - Clinical Translational Focus (AF)*	0.000	1.003	2.349	2.664	-	2.664	2.762	2.817	2.873	2.930	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force training and operational environments such as the mitigation of Musculoskeletal Injury on personnel in Air Force Basic Training and high demand operations. The sub-project areas include: Cognitive Performance which includes assessing Impact of Recurrent Hypobaric Exposure, Physical Performance and Targeted Conditioning which includes providing Evidence Based Prevention Strategies and Health Programs for Optimal Performance, and Identification of Clinical Solutions to Mitigate Operational and Environmental Challenges to Performance. Optimization of Human Capital Selection: Prognostic parameters to the success of airmen in various career field in particular sustain Airmen Trainee Health. These will include selection in mental, social, and physical determinants. These also may include genomic indicators that might suggest physical and mental resiliency to different occupational stressors (tasks, environment, etc.…) and indicators to recovery to baseline to different occupational stressors or frank injury/disease.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Human Performance R&D - Clinical Translational Focus (AF)	1.003	2.349	2.664
Description: This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force training and operational environments such as the mitigation of Musculoskeletal Injury on personnel in Air Force Basic Training and high demand operations. The sub-project areas include: Cognitive Performance which includes assessing Impact of Recurrent Hypobaric Exposure, Physical Performance and Targeted Conditioning which includes providing Evidence Based Prevention Strategies and Health Programs for Optimal Performance, and Identification of Clinical Solutions to Mitigate Operational and Environmental Challenges to Performance. Optimization of Human Capital Selection: Prognostic parameters to the success of airmen in various career field in particular sustain Airmen Trainee Health. These will include selection in mental, social, and physical determinants. These also may include genomic indicators that might suggest physical and mental resiliency to different occupational stressors (tasks, environment, etc.…) and indicators to recovery to baseline to different occupational stressors or frank injury/disease.			
FY 2016 Accomplishments: Introduce early prevention, diagnosis, treatment, and evidence-based training through curriculum modification within U.S. Air Force basic training. Develop clinical and training protocols, in cooperation with military training instructors and clinical treatment teams, to evaluate and improve overall trainee and active duty fitness (e.g., by measuring fitness assessment scores), health and nutrition and augment the capabilities and professional growth of independent duty medical technicians (IDMTs). Evaluate U.S.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284C / *Core Human Performance R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Air Force basic military trainees with non-fracture lower extremity musculoskeletal injuries for clinical and operational outcomes to determine if gait and activity modification by a certified athletic trainers reduces the risk of progression to lower extremity stress fracture and decreases the discharge rate and days of training lost for lower extremity injuries. Demonstrate exposure to non-hypoxic hypobaria induces subcortical white matter injury by MRI. Evaluate changes in inflammatory serum markers of hyperoxemia/oxidant stress. Mature a comprehensive program working to define and mitigate the extreme physiological and physical demands of higher altitudes to include decompression sickness and hypoxia. Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions magnify each other. Advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention.			
FY 2017 Plans: Introduce early prevention, diagnosis, treatment, and evidence-based training through curriculum modification within U.S. Air Force basic training. Develop clinical and training protocols, in cooperation with military training instructors and clinical treatment teams, to evaluate and improve overall trainee and active duty fitness (e.g., by measuring fitness assessment scores), health and nutrition and augment the capabilities and professional growth of independent duty medical technicians (IDMTs). Evaluate U.S. Air Force basic military trainees with non-fracture lower extremity musculoskeletal injuries for clinical and operational outcomes to determine if gait and activity modification by a certified athletic trainers reduces the risk of progression to lower extremity stress fracture and decreases the discharge rate and days of training lost for lower extremity injuries. Continue work to demonstrate exposure to non-hypoxic hypobaria induces subcortical white matter injury by MRI. Evaluate changes in inflammatory serum markers of hyperoxemia/oxidant stress. Evaluate model of hypobaria-related white matter damage for detection of the biological/ neuropathological indicators. Mature a comprehensive program working to define and mitigate the extreme physiological and physical demands of higher altitudes to include decompression sickness and hypoxia. Advance understanding of training and operational environment as it pertains to new accessions, medical readiness, injury reduction, and retention. Advance understanding of musculoskeletal injury in operational environment and assess new technologies for diagnosis and treatment.			
FY 2018 Plans: Design a comprehensive program to define and evaluate the extreme physiological demands of AETC technical school training students to mitigate fatigue and cognitive overload, reduce injury and improve performance. Advance understanding of appropriate selection pertaining to new accessions, job placement, injury reduction and retention. Develop neuroprotection and/ or neurotreatment therapies designed to mitigate hyperoxemic brain injury/effects. Work to characterize at risk mission sets and operator/aircrew needs to optimize performance in high altitude environment to inform operational changes and determine safe altitudes for long-term exposures.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284C / *Core Human Performance R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Develop model to assess and validate return of investment on embedded medics. Examine biomarkers for cognitive and physiological performance. Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions magnify each other.			
Accomplishments/Planned Programs Subtotals	1.003	2.349	2.664

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284D / *Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
284D: *Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)*	0.000	1.002	2.348	2.663	-	2.663	2.761	2.816	2.872	2.929	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned AF missions. This work addresses unique Air Force operational environments such as the mitigation of physiological and cognitive demand on personnel involved in both piloted and remote piloted aircraft operations. Understanding and measuring aviation performance and developing injury prevention strategies to optimize performance of AF personnel. Identification and mitigation of stress on personnel involved in Intelligence, Surveillance, and Reconnaissance operations. The sub-project areas include: Air Force Aircrew Physiology and Cognition Performance which includes pilot performance monitoring, interventions and fatigue management. AF unique Physical, Psychological, Behavioral and Physiological Performance and Targeted Conditioning Mitigation which includes personalized performance and training techniques for optimal performance, Aviator Injury Prevention and Performance Optimization, Select training and simulation to optimize performance of AF operators and personnel. Optimization of Human Capital, Advancing Medical Readiness for Optimal Performance, and Identification of techniques, treatments, and technical solutions to mitigate Operational and Environmental Challenges to Performance.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)	1.002	2.348	2.663
Description: This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned AF missions. This work addresses unique Air Force operational environments such as the mitigation of physiological and cognitive demand on personnel involved in both piloted and remote piloted aircraft operations. Understanding and measuring aviation performance and developing injury prevention strategies to optimize performance of AF personnel. Identification and mitigation of stress on personnel involved in Intelligence, Surveillance, and Reconnaissance operations. The sub-project areas include: Air Force Aircrew Physiology and Cognition Performance which includes pilot performance monitoring, interventions and fatigue management. AF unique Physical, Psychological, Behavioral and Physiological Performance and Targeted Conditioning Mitigation which includes personalized performance and training techniques for optimal performance, Aviator Injury Prevention and Performance Optimization, Select training and simulation to optimize performance of AF operators and personnel. Optimization of AF Human Capital, Advancing Medical Readiness for Optimal Performance, and Identification of techniques, treatments, and technical solutions to mitigate Operational and Environmental Challenges to Performance.			
FY 2016 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284D / *Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Continue assessment of in-flight pilot performance monitoring. Begin assessment of potential physiological measures capable of capturing physiological and cognitive state of AF pilot and operator personnel. Evaluate current/planned technologies employed in current generation aircraft against human performance limitations to address changes needed to technology or identify performance optimization techniques. Conclude efforts identifying the effects of combining over-the-counter stimulants with Modafinil, which may stimulate the need for further research. Apply results from high altitude and hypoxia studies to refine this line of research and potentially spur operational and training changes, and identify areas needed for further research. Implement plans to pursue human systems integration studies, focusing on identified gaps. Conduct operational based vision research. Completed assessment of physiological measures capable of capturing physiological and cognitive state of AF pilot and operator personnel. ***FY 2017 Plans:*** Continue assessment of in-flight pilot performance monitoring. Begin development of performance assessment tool to assess cognitive state of AF pilot and operator personnel. Evaluate current/planned technologies employed in current generation aircraft against human performance limitations to address changes needed to technology or identify performance optimization techniques. Examine and valid biomarkers for cognitive and physiological performance. Continue to collect data and assess results from high altitude and hypoxia studies to refine this line of research to define what is a “safe” altitude, potentially spur operational changes, and identify areas needed for further research. Identify, assess, and validate measurable vision standards for high risk and high demand airman career fields. Develop advanced technologies for vision testing to optimize performance in challenging environments. Assess and validate operationally based psychological, behavioral, and physical requirements to optimize duty performance. Advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention in aeromedical, aerospace, and operational environments. Develop an Optimization of AF Human Capital plan to modernize airman mission alignment. Implement plans to pursue human systems integration studies, focusing on identified gaps. ***FY 2018 Plans:*** Complete capability advancement and finalize in-flight pilot respiratory monitoring system. Finalize performance assessment tool development activities and plan for initial test in a lab and operational environment. Implement findings from the integration of high altitude and hypoxia studies to support and initiate acceleration and altitude research to meet pilot/aircrew mission needs. Continue assessment and validation of vision standards for high risk and high demand airman career fields Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions magnify each other. Implement Optimization of AF Human Capital plan focused on medical readiness to support airman mission alignment.			
Accomplishments/Planned Programs Subtotals	1.002	2.348	2.663

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284D / *Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.***

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 285A / *Operational Medicine Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	16.914	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Operational Medicine Thrust Area develops validated solutions for the delivery of preventative care, intervention and treatment to Active Duty members and DoD beneficiaries. The primary focus areas include: physiologic and psychological health; sub-topics include resilience, personalized medicine, patient safety, and care coordination. Basic research initiatives are developed and translated into practice; advanced technology initiatives are focused on prevention and treatment of chronic disease such as obesity and diabetes. Personalized medicine focuses on genomic issues related to autism, asthma, and obesity.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Operational Medicine Research & Development (Air Force)	0.000	0.000	0.000
Description: The Operational Medicine Thrust Area develops validated solutions for the delivery of preventative care, intervention and treatment to Active Duty members and DoD beneficiaries. The primary focus areas include: physiologic and psychological health; sub-topics include resilience, personalized medicine, patient safety, and care coordination. Basic research initiatives are developed and translated into practice; advanced technology initiatives are focused on prevention and treatment of chronic disease such as obesity and diabetes. Personalized medicine focuses on genomic issues related to autism, asthma, and obesity. ***FY 2016 Accomplishments:*** No funding programmed. ***FY 2017 Plans:*** No funding programmed. ***FY 2018 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 285A / *Operational Medicine Research & Development (Budgeted) (AF)*

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 285B / *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
285B: *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	0.000	0.929	1.147	1.350	-	1.350	2.351	2.757	2.812	2.868	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Operational Medicine Thrust Area develops validated solutions for the delivery of preventative care, intervention and treatment to Active Duty members and DoD beneficiaries. The primary focus areas include: physiologic and psychological health; sub-topics include resilience, personalized medicine, patient safety, and care coordination. Basic research initiatives are developed and translated into practice; advanced technology initiatives are focused on prevention and treatment of chronic disease such as obesity and diabetes. Personalized medicine focuses on genomic issues related to autism, asthma, and obesity.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Operational Medicine R&D - Clinical Translational Focus (AF)	0.929	1.147	1.350

Description: The Operational Medicine Thrust Area develops validated solutions for the delivery of preventative care, intervention and treatment to Active Duty members and DoD beneficiaries. The primary focus areas include: physiologic and psychological health; sub-topics include resilience, personalized medicine, patient safety, and care coordination. Basic research initiatives are developed and translated into practice; advanced technology initiatives are focused on prevention and treatment of chronic disease such as obesity and diabetes. Personalized medicine focuses on genomic issues related to autism, asthma, and obesity.

FY 2016 Accomplishments:

Optimize physiologic conditions during free composite tissue transfer, ameliorate ischemia/reperfusion injury, and maximize reconstructive reliability. Perform allo-transplantation with donor tissue applied drug eluting microspheres, immunocloaking, and additional donor tissue specific treatments to minimize immunoreactivity and produce successful immunotolerance in a large animal model. Optimization of tissue reliability, minimization of inflammatory response, and eventual induction of immunotolerance will aid in vastly expanding and improving reconstructive outcomes in injured service members as well as restoration of long-term near-normal form and function. Evaluate donor graft targeted immunomodulation in a vascularized composite tissue model to reduce the requirement for systemic immunosuppression in reconstructive transplantation. Evaluate advanced techniques for mitigation of ischemia-reperfusion injuries to improve reliability of composite tissue transfer and provide translatable principles for immediate application to battlefield injuries. Establish the feasibility of systemic reloading of graft-implanted hydrogels to prolong free graft survival with minimal systemic drug exposure by comparing drug levels in Reconstructive Transplantation (RT) tissue components (skin, muscle, or draining lymph nodes) to systemic blood levels using mass spectrophotometry, clinicopathologic correlation, cellular, antibody, cytokine, proteomic and genomic profiling, and immunomonitoring (cytokine, gene and cellular transcripts). Examine Hypertonic saline (HTS) use following damage control laparotomy (DCL) to decrease the time to primary fascial closure (PFC) and reduce the number of complications associated with an open abdomen. Determine

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 285B / *Core Operational Medicine R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
the safety of adding autologous stromal vascular fraction (SVF) cells to a standard fat graft and if the added cryostored SVF cells improve fat graft outcomes in soft tissue to advance new techniques in regenerative medicine that promote repair (by the subject's own body tissues) of the post-treatment defect. Examine the use of sub-dissociative dose ketamine (SDDK) for the treatment of acute exacerbations of chronic pain in an emergency department setting to reduce the amount of opioids required for adequate control of pain and to limit the number of adverse effects associated with treatment. Characterize increasing treatment of warriors on long-term opioids for quality and safety of care to decrease adverse events and reduce unintentional drug overdose deaths. Develop and test the feasibility and impact of a prescription monitoring surveillance and intervention tool for identifying nonmedical use of scheduled opioids. Evaluate the utility of behavioral therapies for opioid addiction to protect against relapse. Determine whether clinically available medications that can reverse effects of typical dissociatives might also reverse the effects of synthetic cannabinoids, providing treatment options for emergency room administration of medications to individuals intoxicated with synthetic cannabinoids and suffering from the resulting acute dissociative effects. Perform longitudinal data analyses to develop a brief self-report screener for use in military training that will identify couples at risk for negative relationship outcomes. Characterize effectiveness measures MiCare implementation on Patient Centered Medical Home (PCMH) to improve evidence-based quality care, ensure appropriate patient utilization/provider productivity, and enhance perception of patient–provider communication and workflow satisfaction.			
FY 2017 Plans: Further identify practical health delivery platforms using health services research to adapt innovative, evidence-based health solutions to improve troop to beneficiary health. Pilot feasibility studies and expand to large scale, standardized implementation research to address current high diagnoses rates of musculoskeletal pain, anxiety/depressive disorders, autism, obesity and other chronic disease states. Research health priorities using data analytics to define and validate occupational and physical health performance measures to identify degrees of health needed to optimize, sustain and enhance health practices to improve troop reliability. Initiate research to enhance accession health and minimize/prevent training injury patterns. Assess the physical and psychological/cultural impact of Women in Combat. Research and incorporate health information technology to develop clinical communication networks to train providers and engage beneficiaries through integrated communities of care. Utilize patient genomic information to individualize population health services. Continue regenerative/reconstructive research to validate technologies for surgical reconstruction of service members with previously non-reconstructable injuries. Expand composite tissue transfer to replantation of traumatic amputations and to advanced reconstruction with composite tissue allotransplantation. Provide guidance on the clinical impact of the new cell-based therapies as applied to improvements in fat grafting for warfighters requiring IED and burn wound reconstruction, and beneficiaries with other traumatic injuries. Continue development in the areas of chronic pain following traumatic brain injury, post-traumatic stress disorder, and substance abuse. Implement risk mitigation system to identify non-medical use of opioids in a military setting. Adapt a stepped, couple relationship-skills intervention that fits within a			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 285B / *Core Operational Medicine R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
military training context and evaluate its effectiveness at improving future outcomes for military couples. Provide a comprehensive interpretation of PCM team productivity and clinic workflow post-MiCare implementation. ***FY 2018 Plans:*** Continue CUS enrollment and data analysis for inclusion in the digital BioBank prototype. Initiate research to examine the pharmacogenomics of anti-depressants and anti-psychotics within framework of emerging infrastructure as well as research to identify variants associated with differential response to trauma. Continue support for the AFMS Clinical Utility Study to include additional enrollment to expand the existing AFMS cohort, analysis of impact of genomic risk data on study participants, investigation of diseases and conditions of operational importance. Continue Enabling Personalized Medicine through Exome Sequencing in the U.S. Air Force project.			
Accomplishments/Planned Programs Subtotals	0.929	1.147	1.350

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 285C / *Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
285C: *Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	0.928	1.147	1.349	-	1.349	2.351	2.757	2.812	2.868	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to provide research and development affecting AF beneficiary populations requiring specialized handling during routine medical care such as pilots, RPA operators, special tactics operators and personnel reliability program members. Research will evaluate and determine if special approaches to personal health and performance are required for these beneficiaries. It will also ascertain if conditions not found in the general patient population are applicable to those in this area of interest and conversely if there are conditions or trends in this population requiring attention that are not normally found in the general AF/DoD beneficiary pool. Overall research in this project will support optimization of health care delivery services to all AF/DoD beneficiaries but will focus on high-value asset personnel.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)	0.928	1.147	1.349

Description: This project area seeks to provide research and development affecting AF beneficiary populations requiring specialized handling during routine medical care such as pilots, RPA operators, special tactics operators and personnel reliability program members. Research will evaluate and determine if special approaches to personal health and performance are required for these beneficiaries. It will also ascertain if conditions not found in the general patient population are applicable to those in this area of interest and conversely if there are conditions or trends in this population requiring attention that are not normally found in the general AF/DoD beneficiary pool. Overall research in this project will support optimization of health care delivery services to all AF/DoD beneficiaries but will focus on high-value asset personnel.

FY 2016 Accomplishments:

Conduct research into select AF Flight Medicine enrollees identifying health and performance preventative and intervention needs. Evaluate human performance practice on general AF populations identifying success and areas of improvement required. Perform evaluation of aeromedical care service delivery methods assessing for efficacy and efficiency in promoting beneficial outcomes in operators and their families.

FY 2017 Plans:

Further advance understanding of health and performance practice on general AF populations identifying successes and areas of improvement required to mature comprehensive research programs. Continue to evaluate aeromedical care service delivery methods assessing for efficacy and efficiency in promoting beneficial outcomes in operators and their families. Initiate research program to identify biomarkers of traumatic brain injury in warfighters using minimally invasive sample collection methods to improve aeromedical patient care. Continue development of autonomously designed DNA-based therapeutic interventions against

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 285C / *Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
emergent infectious diseases. Explore an integrated operational medicine approach to characterize individual health and provide comprehensive treatment to improve human health and performance. ***FY 2018 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	0.928	1.147	1.349

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	40.028	6.920	7.725	5.034	-	5.034	5.135	5.237	5.342	5.449	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to detect and identify the USAF and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force)	6.920	7.725	5.034
Description: This project area seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to detect and identify the USAF- and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need. ***FY 2016 Accomplishments:*** Continue evaluating foreign made, clinical lasers to validate that the devices meet U.S. safety and health standards. Continue the investigation of biomarkers associated with laser lesions, which is exploring the biophysical interactions between directed energy and biological tissue at optical frequencies. Continue developing a retinal injury atlas database for use by clinicians and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Start transition to the AF public health community a recently developed compact, insulated, leak-proof, laboratory-approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory; also, explore technology transfer potential to the civilian public health sector. Continue research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Complete studies to further improve HAPSITE capabilities to detect other classes of chemicals. Complete the Problem Definition Study (PDS) to develop a Portfolio Management Tool to define a research strategy that identifies critical and specific phased research studies and technology developments that are required to detect and characterize airborne pollution hazards in the deployed environment with specific relevance to the AF. Perform field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant emerging exposure hazards; nanomaterials, directed energy weapons, newly detected operational chemicals. Continue genomic studies to include analysis of conditions with operational and clinical importance, based on an assessment of AFMS needs. Develop methodologies that are extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Develop nanoparticle sensing prototype for infectious disease threat identification and surveillance. Develop capabilities for remote sensing. Address the enhancement of health risk assessment capabilities to detect, measure and assess biological, chemical, directed energy and other physical contaminants in the environment during deployments and operations, mitigating the consequences of hazardous health exposures and allowing for the restoration of safe use of essential contaminated resources.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference. Provide an analysis of the Chagas disease threat within high-risk military populations to determine if force health protection measures should be implemented to decrease exposure risk. Transition a compact, deployable tool for blood-oxygen-level dependent MRI with neurofeedback to modulate hyperactivity of the auditory cortex and reduce tinnitus symptoms as the first compact tool that can be used outside of the MR environment. Monitor service members periodically for the efficacy of surgical treatment for their non-battle musculoskeletal injury and analyze trends of injury (e.g., gender- service, and age-specific trends) as well as rates for subsequent surgery whether at the site of the index injury or on the contralateral side. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue CUS enrollment and data analysis as well as development of a digital BioBank prototype. Initiate projects to support transition of nano-biodressing to address wound remediation and healing. Initiate research to examine the pharmacogenomics of anti-depressants and anti-psychotics within framework of the NIH MEDSEQ infrastructure as well as research to identify variants associated with differential response to trauma. Complete three studies on topics that include statin pharmacogenomics, genetic risk testing and coaching, and analysis of epigenetics associated with stress and high altitude. Continue support for the AFMS Clinical Utility Study to include additional enrollment to expand the existing AFMS cohort, analysis of impact of genomic risk data on study participants, investigation of diseases and conditions of operational importance. Continue to mature methodologies and requirements for Air Force Medical System bioinformatics tools and processes, including the development of the AFMS digital Biobank. Increase support for Integrative Medicine efforts to provide advancement of research into complementary and alternative medicine (CAM) programs to identify safe and effective therapies to treat patients. CAM therapies will serve as an adjunct to conventional therapies for a holistic approach to patient management. Continue to expand efforts to identify Advanced Diagnostics to include telemedicine initiatives and other advanced technology solutions; and leveraging of computational biology research. Development of a digital Biobank to be used as a platform for the clinical implementation of genomic medicine with the capability to combine and create genomic data registries for use in research missions which will help collaborators to extract and transfer data in a virtual portal and create a test bed for methodologies and protocols for security, storage and integration of genomic data. Advanced Diagnostics program cost is $2.500M per year; and the Integrative Medicine program is $2.800M per year. Both programs supports the AFMS' strategic goals under Enterprise Management, specifically E3 (Define Requirements and Utilize Emerging Knowledge, Research and Technology) and E6 (Empower Continuous Process Improvement and Innovation). ***FY 2017 Plans:*** Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Start transition to the AF public health community a recently developed compact, insulated, leak-proof, laboratory-			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory; also, explore technology transfer potential to the civilian public health sector. Continue research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Complete studies to further improve HAPSITE capabilities to detect other classes of chemicals. Complete the Problem Definition Study (PDS) to develop a Portfolio Management Tool to define a research strategy that identifies critical and specific phased research studies and technology developments that are required to detect and characterize airborne pollution hazards in the deployed environment with specific relevance to the AF. Perform field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant emerging exposure hazards; nanomaterials, directed energy weapons, newly detected operational chemicals. Begin Development of novel tools for pathogen identification. Develop targeted mitigations for white matter hyperintensity abnormalities. Continue to evaluate leading causes of missed training time and medical attrition from training, significantly affect military readiness, to improve the health and well-being of trainees and active duty service members; save significant money from the associated medical and non-medical costs, including long-term disability costs; and improve operational readiness by eliminating disruptions in the training pipeline. Continue subject enrollment for analysis of the Chagas disease threat within high-risk military populations and implement force protection measures to decrease exposure risk. Advance force health protection in the area of occupational and environmental health by delivering real time detection and identification of airborne biological health hazards at the detector's point of operation and improving capabilities of Air Force Medical Service Preventive Medicine personnel by providing rapid detection and notification of the presence of infectious disease agents. Continue the development of new strategies for prevention, identification, and treatment of injuries caused by emerging biological, chemical, directed energy and other physical threats. Continue to develop rapid, ruggedized, field-forward methodologies to detect health threats, including the ongoing evaluation of nanoparticle sensing prototypes for infectious disease threat identification and surveillance. Identify new molecular targets (plasma markers) for enhanced detection and prevention. Provide further analysis of genetic, epigenetic, proteomic and pharmacogenetic testing to advance force health protection measures within the AFMS. Advanced Diagnostics program cost is $2.500M per year; and the Integrative Medicine program is $2.800M per year. Both programs supports the AFMS' strategic goals under Enterprise Management, specifically E3 (Define Requirements and Utilize Emerging Knowledge, Research and Technology) and E6 (Empower Continuous Process Improvement and Innovation). ***FY 2018 Plans:*** Continue as planned in FY17.			
Accomplishments/Planned Programs Subtotals	6.920	7.725	5.034

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
307C: *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	0.000	0.545	1.500	2.235	-	2.235	2.295	2.341	2.388	2.435	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to detect and identify the USAF and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Force Health Protection R&D - Clinical Translational Focus (AF)	0.545	1.500	2.235
Description: This project seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018

detect and identify the USAF and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need.

FY 2016 Accomplishments:

Continue evaluating foreign made, clinical lasers to validate that the devices meet U.S. safety and health standards. Continue the investigation of biomarkers associated with laser lesions, which is exploring the biophysical interactions between directed energy and biological tissue at optical frequencies. Continue developing a retinal injury atlas database for use by clinicians and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Start transition to the AF public health community a recently developed compact, insulated, leak-proof, laboratory-approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory; also, explore technology transfer potential to the civilian public health sector. Continue research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Complete studies to further improve HAPSITE capabilities to detect other classes of chemicals. Complete the Problem Definition Study (PDS) to develop a Portfolio Management Tool to define a research strategy that identifies critical and specific phased research studies and technology developments that are required to detect and characterize airborne pollution hazards in the deployed environment with specific relevance to the AF. Perform field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant nanomaterials. Proposed expansion of Genomic Studies to include analysis of conditions with operational and clinical importance, based on an assessment of AFMS needs. Continue AFMS Innovation initiatives including demonstration projects for process improvements, leadings practices, disruptive and transformative technologies. Analysis of genomics survey data to identify gaps in genomic education, and development of educational programs to correct these gaps. Utilization of patient modeling algorithms to identify pharmacogenomic interventions that can improve patient health and reduce healthcare costs across the AFMS. Provide further analysis in educational interventions for the proper use of genetic testing within the AFMS. Research for pharmacogenomics for anti-depressents and pain medication within the AFMS. Analysis of methodologies and challenges associated with the establishment of an AFMS genome data repository for future implementation of genomic medicine. To augment capabilities for genomic research within the AFMS, the USAF will continue participation in National Human Genome Institute pharmacogenomic research projects. Continue to develop a high-content, rapid throughput toxicological capability with pluripotent cells allowing

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
for a rapid screening of possible threats in the aerospace environment. Develop methodologies that a extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Perform a comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed. Complete evaluating foreign made, clinical lasers to validate that the devices meet U.S. safety and health standards. Complete the investigation of biomarkers associated with laser lesions, which is exploring the biophysical interactions between directed energy and biological tissue at optical frequencies. Continue developing a retinal injury atlas database for use by clinicians and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Complete the transition to the AF public health community a recently developed compact, insulated, leak-proof, laboratory-approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory. Complete the technology transfer to the civilian public health sector. Complete research to develop miniaturized sensors to identify hypoxic/ toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Develop new and innovative technologies to detect and assess hazardous chemical, biological, and physical agents relevant to AF deployment and garrison operations. Initiate studies identified the Problem Definition Study (PDS) and research strategy to detect and characterize airborne pollution hazards (to include burn pits) in the deployed environment. Continue field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant nanomaterials. Continue AFMS Innovation demonstration initiatives, including process improvements, leadings practices, disruptive and transformative technologies. Continued support for the AFMS Clinical Utility Study to include initial analysis of impact of genomic risk data on study participants. Analysis of recruited AF cohorts for diseases and conditions of operational importance. Continued support for research into educational interventions for the proper use of genetic testing within the AFMS and pharmacogenomics research regarding the use of anti-depressants and pain medication within the AFMS. Implementation of genomic education program at USAF testing facility to measure impact of education on genetic test utilization, clinical care, and patient outcomes. Pharmacogenomic demonstration projects at AFMS sites and AF MTFs to test the impact on patient health and healthcare costs. Investigation of methodologies and requirements for Air Force Medical System bioinformatics tools and processes, including the development of the AFMS digital Biobank and the integration of genomic data into clinical workflow through the development of predictive modeling clinical decision support tools that integrate with Electronic Medical Records. Continue to develop a high-content, rapid throughput toxicological capability with pluripotent cells allowing for a rapid screening of possible threats in the aerospace environment.			
FY 2017 Plans: Continue to evaluate leading causes of missed training time and medical attrition from training, significantly affect military readiness, to improve the health and well-being of trainees and active duty service members; save significant money from the			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
associated medical and non-medical costs, including long-term disability costs; and improve operational readiness by eliminating disruptions in the training pipeline. Continue subject enrollment for analysis of the Chagas disease threat within high-risk military populations and implement force protection measures to decrease exposure risk. Advance force health protection in the area of occupational and environmental health by delivering real time detection and identification of airborne biological health hazards at the detector's point of operation and improving capabilities of Air Force Medical Service Preventive Medicine personnel by providing rapid detection and notification of the presence of infectious disease agents. Continue the development of new strategies for prevention, identification, and treatment of injuries caused by emerging biological, chemical, directed energy and other physical threats. Continue to develop rapid, ruggedized, field-forward methodologies to detect health threats, including the ongoing evaluation of nanoparticle sensing prototypes for infectious disease threat identification and surveillance. Identify new molecular targets (plasma markers) for enhanced detection and prevention. Provide further analysis of genetic, epigenetic, proteomic and pharmacogenetic testing to advance force health protection measures within the AFMS.			
FY 2018 Plans: Continue to evaluate leading causes of missed training time and medical attrition from training, significantly affect military readiness, to improve the health and well-being of trainees and active duty service members; save significant money from the associated medical and non-medical costs, including long-term disability costs; and improve operational readiness by eliminating disruptions in the training pipeline. Advance force health protection in the area of occupational and environmental health by delivering real time detection and identification of airborne biological health hazards at the detector's point of operation and improving capabilities of Air Force Medical Service Preventive Medicine personnel by providing rapid detection and notification of the presence of infectious disease agents. Continue the development of new strategies for prevention, identification, and treatment of injuries caused by emerging biological, chemical, directed energy and other physical threats. Continue to develop rapid, ruggedized, field-forward methodologies to detect health threats, including the ongoing evaluation of nanoparticle sensing prototypes for infectious disease threat identification and surveillance. Identify new molecular targets (plasma markers) for enhanced detection and prevention Continue development of the Individual Longitudinal Exposure Record (ILER) and the Individual Exposure Health Risk Profiles (IEHRP) by continuing the three-phased approach for the development and support implementation of IEHRP: 1. Develop statistically validated algorithms that determine health risk profiles and drive preventative course of action (COA) strategies for individuals based on: i) genetic factors, ii) multivariate occupational, lifestyle, and environmental exposure factors, iii) medical pre-disposition, iv) protective factors, and v) other variables that affect their exposure health risk (collectively known as Individual Exposure Health Risk Profiles or IEHRP). 2. Establish an implementation plan to apply individual clinical, genetic and exposure data to IEHRP models that result in risk profiles to inform individuals for preventative behaviors and improved health outcomes.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
3. Design and support execution of research studies to include: (a) establishing test cohorts and clinical studies for genetic and exposure data collection, (b) sensor technology review, (c) selection and execution of genetic testing methods, and (d) IEHRP model analysis and results reporting.			
Accomplishments/Planned Programs Subtotals	0.545	1.500	2.235

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307D / *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
307D: *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.400	1.500	2.235	-	2.235	2.295	2.341	2.388	2.435	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area conducts research to identify, evaluate and control occupational hazards in the workplace-including all settings such as deployed, in the aircraft, in the industrial (in garrison) environment or during emergency response. Information gained means risks are more fully understood with respect to potential mission impact or long-term health effect (Go vs. No Go above some pre-defined hazard level). Key focus areas include a better understanding of dosing, rates of dosing, and mechanistic effects of chemical, biological, radiological, directed energy, and other occupational exposure threats. This includes subtle cognitive effects where there is potential mission impact. Technological opportunities towards non-invasive sensing of the human and the environment are growing and can be exploited to enhance understanding of the risks and enable development of appropriate mitigation and treatment options.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)	0.400	1.500	2.235

Description: This project area conducts research to identify, evaluate and control occupational hazards in the workplace-including all settings such as deployed, in the aircraft, in the industrial (in garrison) environment or during emergency response. Information gained means risks are more fully understood with respect to potential mission impact or long-term health effect (Go vs. No Go above some pre-defined hazard level). Key focus areas include a better understanding of dosing, rates of dosing, and mechanistic effects of chemical, biological, radiological, directed energy, and other occupational exposure threats. This includes subtle cognitive effects where there is potential mission impact. Technological opportunities towards non-invasive sensing of the human and the environment are growing and can be exploited to enhance understanding of the risks and enable development of appropriate mitigation and treatment options.

Improve the early detection, real time prediction of bioenvironmental impact, disease outbreak and intervention, data analytics and information sharing. Develop and demonstrate the rapid transition of analytics tools that convert a multitude of health related data sources into actionable information based on operational context. This will support quick decision targeting of health environmental threats, disease outbreaks, and training and operational assessment alternatives. Major focal areas include: environmental, health history and physiological.

FY 2016 Accomplishments:

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307D / *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Continue to develop a high-content, rapid throughput toxicological capability with pleuripotent stem-cells allowing for a rapid screening of possible threats in the aerospace environment that includes genetic uncertainty in the risk assessment. Develop and validate devices or methods that are extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Perform comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed. Develop capabilities for remote sensing of environmental hazards. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference. Perform assessment of subtle cognitive and respiratory effects of low-level exposures from low-level exposures in the challenging environments associated with AI operations. Continue to study the role of the gut microbiome relevance to deployed airmen health and performance.			
FY 2017 Plans: Continue to develop a high-content, rapid throughput toxicological capability with pleuripotent stem-cells allowing for a rapid screening of possible threats in the aerospace environment that includes genetic uncertainty in the risk assessment. Develop and validate devices or methods that are extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Perform comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed. Develop capabilities for remote sensing of environmental hazards. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference. Perform assessment of subtle cognitive and respiratory effects of low-level exposures from low-level exposures in the challenging environments associated with AI operations. Initiate development of automated algorithms that incorporate environmental sensor and risk assessment to determine appropriate mitigation actions in real time as hazards are presented in-flight and in ground operations. Continue to study the role of the gut microbiome relevance to deployed airmen health and performance.			
FY 2018 Plans: Develop and validate devices or methods that are extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Perform comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed. Develop capabilities for remote sensing of environmental hazards. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference. Perform assessment of subtle cognitive and respiratory effects of low-level exposures from low-level exposures in the challenging environments associated with AI operations. Initiate development of automated algorithms that incorporate environmental sensor and risk assessment to determine appropriate mitigation actions in real time as hazards are presented in-flight and in ground operations. Continue to study the role of the gut microbiome relevance to deployed airmen health and performance. Continue early detection, real time prediction of bioenvironmental impact, disease outbreak and intervention, data analytics and information sharing. Continue development			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307D / *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
and demonstration of the rapid transition of analytics tools that convert a multitude of health related data sources into actionable information based on operational context. Develop a communications platform that can collected exposure and health care data from multiple sources and transmit that data in a compressed format.			
Accomplishments/Planned Programs Subtotals	0.400	1.500	2.235

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	12.160	1.180	1.160	1.560	-	1.560	1.591	1.623	1.655	1.689	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Expeditionary Medicine Research & Development (Air Force)	1.180	1.160	1.560

Description: This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.

FY 2016 Accomplishments:

Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, cryopreserved blood products, rhabdomyolysis and ischemia-reperfusion injury. Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Begin studies to test and compare point of care testing devices for field use. Continue identification of biomarkers and development of decision support algorithms which predict the need for life saving interventions. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics.

Investigate lifesaving hemorrhage control product that can be introduced to the field of combat casualty care as lifesaving interventions. Determine the efficacy of advanced hemorrhage control technologies including X-Stat and small bore X-Stat

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
in models of uncontrolled hemorrhage. Evaluate prehospital and En-Route analgesic use in traumatically injured patients to decrease post-treatment morbidity and mortality. Conduct a study evaluating Cytosorb®TM for removing myoglobin in patients with rhabdomyolysis, or the breakdown of skeletal muscle, to decrease death associated in patients with AKI. Demonstrate that AHR with current and future capability O2-carrying fluids (whole blood [WB], and multi-function resuscitation fluid [MRF]) improves return of spontaneous circulation (ROSC) and survival with critical care in an otherwise lethal model of non-compressible torso hemorrhage and reversal of hemorrhage induced traumatic cardiac arrest compared to standard of care. Evaluate the efficacy of the Cytosorb® filter in mitigating the deleterious effects of bi-lateral hind limb ischemia reperfusion. Evaluate key components of blood to optimize initial hemostatic resuscitation and promote casualty stabilization. Characterize the effects of trauma and damage control resuscitation at the molecular level in blood from patients with exsanguination shock. Characterize the effects of pharmacological intervention on complement activation and coagulation. Evaluate the ability of complement inhibitors to reduce mortality and morbidity of trauma and hemorrhagic shock. Evaluate long-term outcomes and life-long follow-up of the injured Service Member with vascular injury to address late repair success and functional outcomes. Evaluate improved method for AKI prediction for rapid identification of patients at high risk of AKI with subsequent risk of death. In the context of evolving doctrine involving delayed evacuation times, this information is vital in order to prioritize patients for aeromedical evacuation and in the allocation of scarce resources in the deployed environment. Investigate the near and long-term microvascular damage on normal intimal tissue caused by thoracic endograft stents as the first endovascular therapeutic modality for aortic tears. Evaluate the efficacy of Extra-corporeal life support technologies for "suspended animation" approaches that apply both pharmacological and physiological modalities for reducing the impact of metabolism and cellular damage following traumatic injury. Establish Swine Mesenchymal Stromal Cell Library for use in pre-clinical and translational research pertaining to acute lung injury and adjunct therapies for "suspended animation" technologies. Determine efficacy of Adenosine, lidocaine and magnesium (ALM)/Adenocaine in reducing or ameliorating physiologic dyshomeostasis induced by severe controlled hemorrhage to augment "suspended animation" technologies like deep hypothermia in a small volume, lyophilizable and environmentally stable format.			
FY 2017 Plans: Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, cryopreserved blood products, rhabdomyolysis and ischemia-reperfusion injury. Continue studies to test and compare point of care testing devices for field use. Continue identification of biomarkers and development of decision support algorithms which predict the need for life saving interventions. Begin FDA approval process for mature decision support algorithms. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Continue to evaluate novel hemorrhage control products that utilize alternative technologies to active hemostatic coatings to provide a lower-cost, safer and			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
more versatile solution to various hemorrhage control pathologies across the continuum of care. Demonstrate feasibility of training AHR to Level II/III emergency care providers to increase survivability of hemorrhage induced traumatic cardiac arrest. ***FY 2018 Plans:*** Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, cryopreserved blood products, rhabdomyolysis and ischemia-reperfusion injury. Continue studies to test and compare point of care testing devices for field use. Continue identification of biomarkers and development of decision support algorithms which predict the need for life saving interventions. Begin FDA approval process for mature decision support algorithms. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Continue to evaluate novel hemorrhage control products that utilize alternative technologies to active hemostatic coatings to provide a lower-cost, safer and more versatile solution to various hemorrhage control pathologies across the continuum of care. Demonstrate feasibility of training AHR to Level II/III emergency care providers to increase survivability of hemorrhage induced traumatic cardiac arrest.			
Accomplishments/Planned Programs Subtotals	1.180	1.160	1.560

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 308C / *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
308C: *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	0.000	1.503	1.500	1.497	-	1.497	1.527	1.557	1.589	1.620	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)	1.503	1.500	1.497
Description: This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.			
FY 2016 Accomplishments: Investigate lifesaving hemorrhage control product that can be introduced to the field of combat casualty care as lifesaving interventions. Determine the efficacy of advanced hemorrhage control technologies including X-Stat and small bore X-Stat in models of uncontrolled hemorrhage. Evaluate prehospital and En-Route analgesic use in traumatically injured patients to decrease post-treatment morbidity and mortality. Conducted a pilot study evaluating Cytosorb®TM for removing myoglobin in patients with rhabdomyolysis, or the breakdown of skeletal muscle, to decrease death associated in patients with AKI. Demonstrate that AHR with current and future capability O2-carrying fluids (whole blood [WB], and multi-function resuscitation fluid [MRF]) improves return of spontaneous circulation (ROSC) and survival with critical care in an otherwise lethal model of non-compressible torso hemorrhage and reversal of hemorrhage induced traumatic cardiac arrest compared to standard of care. Evaluate the efficacy of the Cytosorb® filter in mitigating the deleterious effects of bi-lateral hind limb ischemia reperfusion.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308C / *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Evaluate key components of blood to optimize initial hemostatic resuscitation and promote casualty stabilization. Characterize the effects of trauma and damage control resuscitation at the molecular level in blood from patients with exsanguination shock. Characterize the effects of pharmacological intervention on complement activation and coagulation. Evaluate the ability of complement inhibitors to reduce mortality and morbidity of trauma and hemorrhagic shock. Evaluate long-term outcomes and life-long follow-up of the injured Service Member with vascular injury to address late repair success and functional outcomes. Evaluate improved method for AKI prediction for rapid identification of patients at high risk of AKI with subsequent risk of death. In the context of evolving doctrine involving delayed evacuation times, this information is vital in order to prioritize patients for aeromedical evacuation and in the allocation of scarce resources in the deployed environment. Investigate the near and long-term microvascular damage on normal intimal tissue caused by thoracic endograft stents as the first endovascular therapeutic modality for aortic tears. Evaluate the efficacy of Extra-corporeal life support technologies for "suspended animation" approaches that apply both pharmacological and physiological modalities for reducing the impact of metabolism and cellular damage following traumatic injury. Establish Swine Mesenchymal Stromal Cell Library for use in pre-clinical and translational research pertaining to acute lung injury and adjunct therapies for "suspended animation" technologies. Determine efficacy of Adenosine, lidocaine and magnesium (ALM)/Adenocaine in reducing or ameliorating physiologic dyshomeostasis induced by severe controlled hemorrhage to augment "suspended animation" technologies like deep hypothermia in a small volume, lyophilizable and environmentally stable format. ***FY 2017 Plans:*** Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, rhabdomyolysis and ischemia-reperfusion injury. Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Continue to evaluate novel hemorrhage control products that utilize alternative technologies to active hemostatic coatings to provide a lower-cost, safer and more versatile solution to various hemorrhage control pathologies across the continuum of care. Demonstrate feasibility of training AHR to Level II/III emergency care providers to increase survivability of hemorrhage induced traumatic cardiac arrest. ***FY 2018 Plans:*** Continue per FY17 plan.			
Accomplishments/Planned Programs Subtotals	1.503	1.500	1.497

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308C / *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 308D / *Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
308D: *Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	1.502	1.499	1.497	-	1.497	1.527	1.557	1.589	1.620	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to standardize training in use of deployed equipment and supplies because of the increasing number of missions that find teams from different countries working together. Evaluation of skills required in an environment with a lack of air dominance and vast geographic distances in future theaters that increases the tactical field care required and tactical evacuation care phases of casualty care in Role II care that may be unavailable for up to 48 hrs after injury and casualties will be maintained by field providers. Determination of what is required to train peacetime military care providers military medical providers with minimal experience in pre-hospital or acute trauma/critical care yet expert delivery of this care is absolutely required in an austere, isolated environment.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)	1.502	1.499	1.497
Description: This project area seeks to standardize training in use of deployed equipment and supplies because of the increasing number of missions that find teams from different countries working together. Evaluation of skills required in an environment with a lack of air dominance and vast geographic distances in future theaters that increases the tactical field care required and tactical evacuation care phases of casualty care in Role II care that may be unavailable for up to 48 hrs after injury and casualties will be maintained by field providers. Determination of what is required to train peacetime military care providers military medical providers with minimal experience in pre-hospital or acute trauma/critical care yet expert delivery of this care is absolutely required in an austere, isolated environment.			
FY 2016 Accomplishments: Establish the optimal timing to establish a capability when and where needed as expected to meet the "golden hour" requirement and hold patients until movement is available, stabilize and treat during transport, and provide effective, integrated health service support (HSS) across service lines. Assess what resuscitation goals (e.g. evidence-based markers) are required during various phases of patient movement and different patient conditions to improve outcomes.			
FY 2017 Plans: Develop, validate and implement a suite of medical technologies to induce a state of physiology in combat casualties that allows for stabilization and transport without degradation of physiologic status and increases in mortality and morbidity commonly associated with extended pre-hospital transport times in austere combat theaters of operation.			
FY 2018 Plans:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308D / *Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Continue per FY17 plan.			
Accomplishments/Planned Programs Subtotals	1.502	1.499	1.497

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 309A / *Regenerative Medicine (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
309A: *Regenerative Medicine (USUHS)*	22.296	8.775	7.323	7.373	-	7.373	8.327	10.209	10.413	10.621	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USUHS), the Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Regenerative Medicine (USUHS)	8.775	7.323	7.373

Description: The Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center. The CNRM has established 11 research cores and funded 119 research projects.

FY 2016 Accomplishments:

- Clinical studies have enrolled 4,503+ subjects with longitudinal follow up for biomarker discovery and therapeutic outcome studies.

- Clinical studies database aligned with Federal Interagency TBI Research database. Collected 3,551,325+ total data records.

- Biorepositories for biomarker analysis of fluids (65,000+ specimens) and neuropathology (33+ brain donations), specialized for analysis of TBI in service members.
- Expertise and data generated through CNRM projects and access to core resources have been leveraged to develop research beyond that funded by CNRM. USU investigators have been awarded $35,845,358+ in non-CNRM funding.

- Hosted the annual two-day National Capital Area TBI Research Symposium with an average of 400 participants for DoD, HHS, and academic investigators to share basic through clinical research advances and develop collaborative interactions.

- Through Jul. 2016, CNRM has published over 260 peer-reviewed publications, with over 2500 subsequent citations, demonstrating significant impact in the field of TBI research. In addition, CNRM researchers have presented at numerous national and international conferences.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
- Awarded 10 new research projects in Feb. 2016. In addition, received 41 pre-proposals in response to FY16/17 proposal call. After scientific screening, 26 were selected to be submitted for review as full applications, with anticipation of funding 10-12 new projects in Jul. 2017. - Received 2016 Platinum MarCom Award from Association of Marketing and Communications Professionals for CNRM communication booklet. - Developing neuroimaging, neuroassessment, and experimental data to improve classification of TBI patients based on pathophysiology and to evaluate outcome following TBI, with identification of potential military specific exposures based on parallel civilian data (publications) - Developing serum biomarker assays using highly sensitive and specific detection methods for classification of TBI patients and monitoring therapeutic response (publications). - Performing clinical trials for early stage testing of interventions to promote recovery from TBI (publications). ***FY 2017 Plans:*** CNRM objectives include: (1) Continue interdisciplinary, collaborative studies that bring together expertise across USU, WRNMMC, and intramural NIH to address the highest priority TBI research in diagnosis through treatment and recovery as relevant to military service members; (2) Continue operational capability of all Cores to provide efficient research infrastructure with high quality resources and technical expertise; (3)Fund start-up research of one new USU Radiology faculty member to maintain translational neuroimaging capability; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY18 funding;(5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host internal CNRM data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research;(11) Support fellowship program to facilitate neuroscience and regenerative medicine research capabilities at DoD sites in NCA.; (12) Participate on the Traumatic Brain Injury (TBI) Research Synergy Board (RSB) and contribute to the TBI “Unity of Effort” to strategically strengthen and accelerate TBI research on “America’s Health Campus.” ***FY 2018 Plans:***			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
CNRM objectives include: (1) Continue interdisciplinary, collaborative studies that bring together expertise across USU, WRNMMC, and intramural NIH to address the highest priority TBI research in diagnosis through treatment and recovery as relevant to military service members; (2) Continue operational capability of all Cores to provide efficient research infrastructure with high quality resources and technical expertise; (3)Fund Clinical Trials Unit and start-up research of one new USU faculty member to develop clinical research capability; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY17 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host internal CNRM data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research;(11) Support fellowship program to facilitate neuroscience and regenerative medicine research capabilities at DoD sites in NCA; (12) Participate on the Traumatic Brain Injury (TBI) Research Synergy Board (RSB) and contribute to the TBI “Unity of Effort” to strategically strengthen and accelerate TBI research on “America’s Health Campus;” (13) Utilize Biospecimen Bank of blood specimens linked to MRI and clinical assessment data in longitudinal studies of TBI patients and relevant comparison cohorts; (14) Brain Tissue Repository of brains donated from military TBI patients, including state-of-the-art neuropathological analysis of blast cases and relevant comparison cohorts; (15) Deployment of multi-modal forms of advanced imaging technology for diagnosis of TBI, with and without co-morbid PTSD, including MRI-PET, hyperacute MRI, and novel diffusion imaging techniques such as Mean Apparent Propagator; (16) Creation of Work flow pipeline for accurate and efficient analysis of neuroimaging data relevant to TBI, including quantitative analysis of microhemorrhages, traumatic meningeal injury, and white matter abnormalities; (17) Utilize multiple animal models involving multiple species for improved analysis of acute and chronic effects of TBI relevant to the warfighter, including blast exposure, repetitive injury, and stress conditions.			
Accomplishments/Planned Programs Subtotals	8.775	7.323	7.373

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0806721HP: *Uniformed Services University of the Health Sciences*	9.090	9.272	9.458	-	9.458	9.647	9.840	10.036	10.236	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost

Remarks

Provides funding to conduct Natural History study; Infrastructure to support the CNRM program; and salaries of neuroscience faculty and technical and administrative support personnel.

D. Acquisition Strategy

N/A

E. Performance Metrics

Center for Neuroscience and Regenerative Medicine: In FY16 through FY18, identify, design protocols, perform scientific and program reviews, and conduct research in Clinical Core activities such as Phenotyping, Imaging and Imaging Analysis, to aid in patient diagnosis and evaluation.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373A / *GDF - Medical Technology Development*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
373A: *GDF - Medical Technology Development*	395.744	113.011	139.454	126.790	-	126.790	136.578	138.564	147.876	152.262	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development provides funds for development of promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small-scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. Medical technology development is managed by six Joint Program Committees: 1- Medical Simulation and Information Sciences research aims to coordinate health information technology, simulation, and training research across the Military Health System. Technology development efforts are directed toward the medical simulation task. 2- Military Infectious Diseases research is developing protection and treatment products for military relevant infectious diseases. 3- Military Operational Medicine research goals are to develop and validate medical countermeasures against operational stressors, prevent physical and psychological injuries during training and operations, and to maximize health, performance and fitness of Service members. 4- Combat Casualty Care research is optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through en route and facilities care. 5- Radiation Health Effects research focuses on technology development of acute radiation exposure medical countermeasures development. 6- Clinical and Rehabilitative Medicine research is developing knowledge and materiel products to reconstruct, rehabilitate, and provide care for injured Service members. Technology development efforts are directed against tasks in neuromusculoskeletal rehabilitation, pain management, regenerative medicine, and sensory systems.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: GDF – Medical Technology Development	113.011	139.454	126.790

Description: Funds provide for the development of medical technology candidate solutions and components of early prototype systems for test and evaluation. Promising drug and vaccine candidates, knowledge products, and medical devices and technologies are selected for initial safety and effectiveness testing in small scale human clinical trials.

FY 2016 Accomplishments:

Medical simulation and information sciences technology maturation completed the virtual tissue advancement research, which provided open source resources to enable developers to create more appropriate physics-based virtual tissue models for simulators. En Route training research identified gaps and technical issues to define requirements for a Joint Evacuation Training Simulation System. Investigators researched knowledge oriented medical training metrics that can best translate into real patient care / outcomes and to begin the process of linking evidence-based training to patient outcomes. Medical simulation explored advanced adaptive tutors that incorporate adult learning cognitive thinking and neuroplasticity models. Continued research to identify predictive markers to differentiate good and poor medical providers. Advancements were made in augmented reality (AR) technologies by evaluating AR applications for the purpose of pre-intervention rehearsal. A joint Service upper & lower airway trainer prototype was transitioned to the advanced developer. Medical simulation research was conducted on the current and

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
anticipated immediate future technical standards of military healthcare simulation systems in order to inform developers what technical standards are needed to develop future systems. Military infectious diseases research supported an intramural collaborative effort focused on a detailed investigation of combat trauma wound microbiology and infections linked to well-characterized clinical data and outcomes. Focus areas included bacterial microbiome within combat wounds, biofilm production and impact, antimicrobial resistance emergence and impact, and commonly observed microbes and their impact. The overarching goal of this collaborative inter-service effort between DoD clinical and research and development groups was to expand understanding of the complex microbiology inherent within combat wounds in order to lead to improved prevention and treatment. Continued ongoing efforts to develop antimicrobials and managed wound infections to identify novel antimicrobial countermeasures as well as better strategies to prevent/treat wound infections. Diagnostic assays for selected bacteria commonly found in wound infections progressed in development for use on an FDA-approved diagnostic system to enable quicker diagnosis and treatment. These studies aligned with the National Strategy for Combating Antibiotic Resistance. Military operational medicine: Defined the neurological consequences of acute and repeated low level blast exposures of varying intensity and frequency in order to improve exposure standards. Performed research contributing to improved auditory injury standards for application in health hazard assessments, and for predictive models of military performance. Supported the development of guidelines relating to the likelihood of musculoskeletal injury in military training and applicable to operational environments. Developed improved criteria for head supported mass and multisensory cueing in degraded visual environments for fixed wing aircraft. Incorporated behavioral intervention regimens into clinical practice guidelines for the treatment of alcohol feelings and behaviors for the treatment of PTSD to current standards of care. Concluded two large scale projects evaluating compressed treatment delivery (daily psychotherapy as compared to once per week) for PTSD for equivalency between 3-week versus 3-4 month treatment regimens. Initiated large scale study for pre-/post-biomarker changes associated with psychopharmacologic, psychotherapy, and brain stimulation interventions. Refined PTSD blood-based biomarkers for transition to advanced development. Delivered validated interventions for enhanced resiliency in military families and Warfighters and more accurate suicide prevention screening tools. Developed recommendations on dietary supplement interventions to promote resiliency and sustainment of cognitive performance after brain injury. Transitioned policy recommendations to the Services for improving Warfighter nutrition during training and operations. Incorporated decision aids for managing thermal physiological work strain into physiological health status monitoring. Developed strategies to mitigate adverse health and disease outcomes of chemical exposures. Validated stress response biomarkers of pulmonary health resulting from exposures to toxic substances. Combat casualty care hemorrhage research evaluated immune system modulating drugs to treat hemorrhagic shock, focused on validating diagnostic and therapeutic targets for coagulopathy of trauma. Neurotrauma research focused on the development of novel technologies to advance capabilities for the assessment and monitoring of severe TBI casualties further forward, to mitigate			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
secondary brain injury and to maintain stability during prolonged field care. Treatments for Tissue Injury continued to develop a specialized fracture repair product, addressed treatments for acute lung injury, and enhanced limb and craniofacial wound stabilization. Forward Surgical and Critical Care continued to develop the Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) which recently gained FDA approval, for the treatment of acute life-threatening hemorrhage. Forward Surgical and Critical Care also continued to develop technology to detect cardiovascular collapse. En Route Care research studied the physiological impact of patient transport and appropriate time to transport injured patients following injury. Military medical photonics developed technologies that focus on the use of advanced optical technologies, including lasers, spectroscopy, and imaging to develop new kinds of diagnostic and therapeutic tools. The readout system for the lactate sensor was redesigned for greater simplicity, longer life, and to eliminate the need for an internal battery. Commercialization of photochemical tissue bonding for multiple clinical applications was explored. Radiation health effects research began technology development efforts in FY 2016 to evaluate therapeutic candidates for acute radiation exposure and to develop data to support preparation of a technical data package for investigational new drug applications. Clinical and rehabilitative medicine transferred current efforts and down-selected products to industry for neuromusculoskeletal injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Supported development of preclinical and pilot/early-phase clinical evaluations of candidate technologies for restoration, regeneration, rehabilitation, and reintegration strategies and medical products. Neuromusculoskeletal injury supported research efforts focused on rehabilitation and reintegration strategies and devices; prosthetics (devices that restore function); orthotics (devices used to support or supplement a weakened joint or limb); neural interfaces (invasive and non-invasive methods of using the brain and/or nerves in the arms and legs for device control); and the prevention and treatment of secondary deficits (heterotopic ossification, osteoarthritis, etc.). Pain management efforts continued to track pain-related substance abuse; developed novel methods and therapeutics to control pain, including battlefield pain, burn pain, neuropathic pain, and chronic pain after amputation. Studied modulation of inflammatory cells as an approach to mitigate spinal cord injury neuropathic pain. Studied effects of peripherally administered opioids. Developed nerve blocks for knee and hip arthroplasty (joint replacement) in Veterans. Regenerative medicine developed methods for limb and digit salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, repair of skin injury resulting from burns, composite tissue allotransplantation (tissue/organ transplantation between genetically different individuals) and associated immune system modulation technologies and genitourinary (genital and urinary organs) restoration. Studied approaches for immunomodulation and immune engineering to improve outcomes and control rejection following vascularized composite allotransplantation (hand and face transplantation). Sensory systems research advanced diagnosis, restoration and rehabilitation of injured and dysfunctional sensory systems,			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
including vision (total orbit, cornea, retina, and ocular nerve), hearing (hair cells, tympanic membrane, cochlea, auditory nerve) and balance (vestibular complex). ***FY 2017 Plans:*** Medical simulation and information sciences technology maturation is focusing on developing prototypes of simulated skin with intent to attach to existing medical simulators or future advanced modular manikins, to better represent the integumentary system on training systems. Researching existing environmental, physiologic, and other available sensors to assess how data/ information already obtained will influence the strategies on developing future simulation systems. Research and development is occurring in the area of Machine Learning/Artificial Intelligence tools to improve predictive models for medical training and education. Advancing medical simulation systems interoperability to increase sharing of content, data, and information among simulation component devices. Research is also focusing on improving education and training in the area of prolonged field care. Conducting research focusing on using virtual patient technologies to create improved training applications for an array of burn injuries. Military infectious diseases research is continuing to support the on-going inter-service effort between DoD clinical and research and development groups to expand understanding of the complex microbiology inherent within combat wounds in order to lead to improved prevention and treatment. Evaluating results of studies to develop antibacterial and clinical guidelines for better wound infection management and determining down-selection candidates. Progressing in the development of diagnostic assays for selected bacteria commonly found in wound infections for use on an FDA-approved diagnostic system to improve pathogen identification times, which will guide better treatment approaches. Initiating studies aimed at developing innovative drug and vaccine solutions to combat emerging infectious diseases. Releasing program announcements in developing antimicrobials and treating wound infections to address critical research focus areas such as the ability to predict infection and better treatment options for infections with multi-drug resistant organisms. These studies align with the National Strategy for Combating Antibiotic Resistance. Military operational medicine: Researchers are collecting data to validate whole body models of blast injury exposure and develop criteria to determine the optimal spacing of blast exposures to prevent cumulative mild TBI. Developing improved predictive auditory injury models in order to update acoustic injury standards for health hazard assessment. Developing tools to optimize return to duty after lower extremity (foot and ankle) injury, and head supported mass acute and chronic injury predictive models for mounted and dismounted environments. Collecting data to improve multisensory cueing criteria for aircrew performance optimization in degraded visual environments. Utilizing data collected in longitudinal assessments for dietary supplement use and correlate usage patterns with associated negative and positive health effects. Evaluating the effects of healthy cooking on food choice behaviors, nutritional status, and psychological states in Wounded Warriors and their families. Continuing studies evaluating the physical demands associated with selection to historically male military occupations to develop gender-neutral			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Military Occupational Specialty assignment standards. Completing studies to inform alcohol and substance abuse prevention and treatment intervention guidelines. Continue work to deliver validated interventions for promoting resilience in military families and Service members. Delivering interventions to prevent suicide behaviors and begin clinical trials to test the efficacy of the interventions. Concluding several large scale intervention studies evaluating pharmacologic, psychotherapy, and augmented psychotherapy (virtual reality and/or pharmacologic cognitive enhancement) treatments for PTSD. Continuing to build larger scale human PTSD data and specimen banks for meta-analyses, consistent with NRAP guidelines. Validating candidate biomarkers for exposure to inhaled or ingested toxic substances and beginning to develop medical guidance for adverse health risk assessments. Conducting research to provide validated metrics for optimized operational task performance in extreme environments. Combat casualty care hemorrhage research is continuing to evaluate immune system modulating drugs to treat hemorrhagic shock. Work is aimed at validating diagnostic and therapeutic targets for coagulopathy of trauma. Inflammatory modulation work is shifting focus to the time period 4 to 72 hours post injury (relevant to prolonged field care). New work in this area is focusing on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Neurotrauma research is focusing on developing novel technologies and therapeutics to enhance capabilities for the assessment, monitoring, and treatment of moderate and severe TBI casualties in the forward environment. This overarching effort will mitigate secondary brain injury, maintain patient stability during prolonged field care scenarios and ultimately reduce morbidity and mortality. Neurotrauma research is studying the impact of concussion on multiple aspects of military performance in cadets and midshipmen at the Service academies. Treatments for extremity trauma continues the development of a specialized fracture repair product, novel fracture stabilization techniques and is exploring treatments for acute lung injury and maxillofacial wounds. Forward Surgical and Critical Care continues to develop the Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA). Forward Surgical and Critical Care also continues to develop technology to detect cardiovascular collapse. In addition, prehospital research is transitioning to advanced development, including the vascular shunt and decision-assisted tools for prehospital and intensive care units. En Route Care research is developing the specifications of an integrated system to support safe patient care and hand-offs, and the development of expanded en route care interventions and treatment capabilities, to include non-invasive monitoring technologies. The military medical photonics program is developing light-based technologies and systems for combat casualty care and transition to advanced development. Particular emphasis is on creating a portable platform for photo-acoustic imaging, and demonstrating its application to detecting blood pooling in the abdomen and oxygen content in the pulmonary artery. Photochemical cross-linking (the use of light to create new molecular bonds) to strengthen veins for grafting to arteries in wounded warrior surgery is being demonstrated, as are the post-surgical benefits of photochemical bonding (the use of light to create new molecular bonds) in reducing scarring and adhesions. A general theme of the medical photonics program is to develop miniaturized sensors and actuators which can be inserted or implanted for important new kinds of diagnostic and therapeutic benefit.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Radiation health effects research continues to evaluate therapeutic candidates and radioprotectants (Prophylaxes that protect against cell damage caused by radiation) for acute radiation exposure and develop data to support preparation of a technical data package for investigational new drug applications. Research is additionally developing data to support qualification of models for use in FDA approved trials. Clinical and rehabilitative medicine is conducting early human trials of promising products, evaluating preclinical safety of promising treatments, and testing FDA-licensed products in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and sensory systems (hearing, vision, and balance) after traumatic injury. Supporting preclinical and clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation outcomes after Service-related injuries. Evaluating novel therapeutics and devices for pain management. Evaluating preclinical and early clinical safety and efficacy of immunomodulatory technologies, skin substitutes to treat burn injury, treatments for volumetric muscle loss, treatments for segmental bone defects and nerve conduits for nerve injury. Conducting pre-clinical and early clinical trials to advance diagnosis, restoration and rehabilitation of injured and dysfunctional sensory systems, including hearing (hair cells, tympanic membrane, cochlea, and auditory nerve) and balance (vestibular complex). ***FY 2018 Plans:*** Medical simulation and information sciences technology maturation will focus on developing and integrating pharmacodynamics and pharmacokinetics algorithms into an open source physiology research engine and is used to support a repository that contains simulated pharmaceuticals and other resuscitative treatments that are the most relevant to point of injury and en route care training. It will incorporate the side effects of the drugs and drug/drug interactions to elicit how to deal with additional acute reactions. This repository is designed to improve medical simulation and training. Research will also focus on assessment system tools with emphasis on combat casualty care training. Will optimize synthetic materials used in part-task mannequins, full body mannequins, or peripherals that could be used on the Advanced Modular Manikin in order to better represent tissues under different environments. Military infectious diseases research will continue supporting the inter-service effort between DoD clinical and research and development groups to develop novel and innovative therapeutics and delivery technologies for combat wound infections. On-going multi-year studies addressing critical research focus areas in wound infection, such as improved treatment options for infections with multi-drug resistant organisms, will be supported. These efforts will be in alignment with the National Strategy for Combating Antibiotic Resistance. Results of studies to develop antibacterial and clinical practice guidelines for better wound infection management will be evaluated for down-selection. Will continue efforts aimed at partnering with other entities to rapidly accelerate promising, innovative drug and vaccine solutions to combat emerging infectious diseases (e.g., Chikungunya, MERS, Zika).			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Military operational medicine: Researchers will continue to collect blast exposure data to validate whole body models of blast injury exposure in the training environment. Will continue research to refine and improve predictive auditory injury models in order to update acoustic injury standards for health hazard assessment. Will continue to develop tools to optimize return to duty after lower extremity (foot and ankle) injury, and head supported mass acute injury predictive models for mounted and dismounted environments. Will continue to collect data to improve multisensory cueing criteria for aircrew performance optimization in degraded visual environments. Will evaluate longitudinal data collected for dietary supplement use with correlation to usage patterns with associated negative and positive health effects. Will provide guidance on the effects of healthy cooking for food choice behaviors, nutritional status, and psychological states in Wounded Warriors and their families. Will continue studies evaluating the physical demands associated with selection to historically male military occupations to develop gender-neutral Military Occupational Specialty assignment standards. Will conduct research aimed at delivering assessment, prevention, and treatment interventions and tools that mitigate substance abuse, including prescription drug misuse and alcohol and other drug abuse. Will continue to deliver interventions to prevent suicide behaviors and conduct clinical trials to test the efficacy of the interventions. Will begin studies aimed at delivering two resilience building/prevention programs focused on education, skills, and novel service delivery methods for Service member and Family resilience. Will conclude several large scale intervention studies evaluating pharmacologic (drug action), psychotherapy, and augmented psychotherapy (virtual reality and/or pharmacologic cognitive enhancement) treatments for PTSD. Will use newly built and existing large-scale PTSD datasets and state-of-the-art analytic methods to produce individualized treatment guidelines for PTSD as well as PTSD-related sleep disturbances. Will continue to validate candidate biomarkers of exposure to inhaled or ingested toxic substances and develop medical guidance for risk assessment of adverse health outcomes. Will continue to conduct research to provide validated metrics for optimized operational task performance in extreme environments. Will validate novel methods for estimating thermal strain from non-invasive measures. Combat casualty care hemorrhage research will continue to evaluate immune system modulating drugs to treat hemorrhagic shock with a focus on the time period 4 to 72 hours post injury (relevant to prolonged field care). In addition, work will continue on the pathophysiological (functional changes associated with injury) impacts of using advanced hemorrhage (bleeding) control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Will initiate animal studies to evaluate oxygen delivery solutions that can be infused to maintain survivability for potential use in severe casualties where blood transfusion is not available. Neurotrauma research will focus on the development of novel technologies to better assess, monitor and maintain the stability of more severely injured TBI casualties closer to point of injury and during prolonged field care. Precision medicine research will improve the characterization of TBI, develop targeted therapies, devices, clinical guidelines, the impact of pre-injury conditions and the environment to improve the care provided to TBI casualties. Furthermore, neurotrauma research will investigate the impact of pre-injury conditions and the environment on Service member response to treatment and recovery following TBI. The program will also leverage data from Combat Operations to improve management of TBI by correlating injury events and medical records. Treatments for extremity trauma will continue to develop specialized fracture stabilization techniques,			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
address treatments for organ support and stabilization of craniomaxillofacial wounds. Pre-hospital Tactical Combat Casualty Care will develop enhanced surgical procedures and equipment. En Route Care research will continue to develop the specifications of an integrated system to support safe patient care and hand-offs, and the development of expanded En Route care interventions and treatment capabilities, to include non-invasive monitoring technologies. The military medical photonics program will develop light-based technologies and systems for combat casualty care and transition to advanced development. Particular emphasis will be on creating a portable platform for photo-acoustic imaging, and demonstrating its application to detecting blood pooling in the abdomen and oxygen content in the pulmonary artery. Photochemical cross-linking (the use of light to create new molecular bonds) to strengthen veins for grafting to arteries in wounded warrior surgery will be demonstrated, as will the post-surgical benefits of photochemical bonding (the use of light to create new molecular bonds) in reducing scarring and adhesions. A general theme of the medical photonics program will be to develop miniaturized sensors and actuators which can be inserted or implanted for important new kinds of diagnostic and therapeutic benefit. Radiation health effects research will continue to evaluate therapeutic candidates and radioprotectants for acute radiation exposure, and develop data to support preparation of a technical data package for IND applications. Research will develop data to support qualification of models for use in FDA approved trials. Objectives will include demonstrating improved survivability following high doses of radiation exposure with treatment at 24 hours and less after exposure. Clinical and rehabilitative medicine will conduct early human trials of promising products, evaluate preclinical safety of promising treatments, and test FDA-licensed products in the areas of neuromusculoskeletal injury, pain management, and regenerative medicine. Will support clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation outcomes after Service-related injuries. Will evaluate novel therapeutics and devices for pain management. Will assess chronic pain risk factors. Will assess preclinical and early clinical safety and efficacy of technologies designed to alter or regulate immune functions, skin substitutes to treat burn injury, treatments for volumetric muscle loss, treatments for segmental bone defects, and strategies for stabilization or regeneration of neuromuscular junctions for nerve injury.			
Accomplishments/Planned Programs Subtotals	113.011	139.454	126.790

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Mature and demonstrate safety and effectiveness of medical procedures, medical devices, and drug and vaccine candidates intended to prevent or minimize effects from battlefield injuries, diseases, and extreme or hazardous environments. Milestone B packages will be developed to transition products into advanced development.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, quarterly and annual status reports, and Program Sponsor Representative's progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. The benchmark performance metric for transition of research conducted with medical technology development funding is the attainment of maturity level that is typical of Technology Readiness level 6 or the equivalent for knowledge products.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 378A / *CoE-Breast Cancer Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
378A: *CoE-Breast Cancer Center of Excellence (Army)*	32.949	6.750	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Breast Cancer Center of Excellence provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. This approach integrates prevention, screening, diagnosis, treatment and continuing care, incorporation of advances in risk reduction, biomedical informatics, tissue banking and translational research. The project is based on a discovery science paradigm, leveraging high-throughput molecular biology technology and our unique clinically well-characterized tissue repository with advances in biomedical informatics leading to hypothesis-generating discoveries that are then tested in hypothesis-driven experiments. The objective of this research is to reduce the incidence, morbidity (illness), and mortality (death) of breast diseases and breast cancer among all military beneficiaries.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Breast Cancer Center of Excellence	6.750	0.000	0.000
Description: Provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. ***FY 2016 Accomplishments:*** The Breast Cancer Center of Excellence provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. This approach integrates prevention, screening, diagnosis, treatment and continuing care, incorporation of advances in risk reduction, biomedical informatics, tissue banking and translational research. The project is based on a discovery science paradigm, leveraging high-throughput molecular biology technology and our unique clinically well-characterized tissue repository with advances in biomedical informatics leading to hypothesis-generating discoveries that are then tested in hypothesis-driven experiments. The objective of this research is to reduce the incidence, morbidity, and mortality of breast diseases and breast cancer among all military beneficiaries. ***FY 2017 Plans:*** No funding programmed. Funding for Breast Cancer Center of Excellence transferred from Army to USUHS (project 378B) starting in FY 2017. ***FY 2018 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	6.750	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 378A / *CoE-Breast Cancer Center of Excellence (Army)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, incorporation into training curriculum throughout the Military Health System, and other applicable means.

E. Performance Metrics

Performance is judged on the number of active protocols, the number of articles that appear in peer-reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 378B / *CoE-Breast Cancer Center of Excellence (USU)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
378B: *CoE-Breast Cancer Center of Excellence (USU)*	0.000	0.000	9.900	9.088	-	9.088	10.280	10.475	10.685	10.898	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Breast Cancer CoE provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. This approach integrates prevention, screening, diagnosis, treatment and continuing care, incorporation of advances in risk reduction, biomedical informatics, tissue banking and translational research. The project is based on a discovery science paradigm, leveraging high-throughput molecular biology technology and our unique clinically well-characterized tissue repository with advances in biomedical informatics leading to hypothesis-generating discoveries that are then tested in hypothesis-driven experiments.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Breast Cancer Center of Excellence	0.000	9.900	9.088

Description: Breast Cancer CoE provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.

FY 2016 Accomplishments:
No funding programmed.

FY 2017 Plans:
The Uniformed Services University of the Health Sciences (USUHS) has assumed the research oversight of the Breast Cancer Center of Excellence (CoE) in FY 2017. The Breast Cancer CoE will continue to enhance active duty female readiness through study of the increased breast cancer incidence rate in the active duty force by the process of banking biospecimens in the DoD's biorepository, using the repository for intramural/extramural collaborations and secondary usage research. Will use our unique collection of breast cancer biospecimens to study angiogenesis and lymphogenesis in different grades of Ductal Carcinoma In Situ (DCIS) and Invasive Ductal Carcinoma (IDC). Will continue using scientific research to produce better outcomes for our patients (DoD Active Duty, Beneficiaries and Retirees). Further develop an analytical system for integrative data analysis and mining, and develop a breast knowledgebase to support clinical and research activities in the Breast Cancer CoE/Clinical Breast Cancer Program (CBCP). Conduct quantitative analysis of therapy relevant proteins by immunohistochemistry within subclasses of breast cancer to provide better patient selection into clinical trials for targeted and combination therapies. Use state-of-the-art 3D cell culture techniques and modern approaches to study cancer cell biology, study the mechanisms of cell invasion, migration and ultimately metastasis in breast cancer cell lines.

The Breast Cancer CoE will continue to identify genetic changes in low- and high-grade breast tumors to improve our understanding of the evolutionary process of breast cancer and to identify a protein signature that can discriminate low- from

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 378B / *CoE-Breast Cancer Center of Excellence (USU)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
high-grade breast tumors, allowing for more accurate diagnosis and risk assessment. Will continue to incorporate the rapidly growing public genomic and proteomic datasets related to breast cancer into our data warehouse to be able to mine the combined data sets for the generation of new hypotheses regarding breast cancer development, progression and treatment. Will further collaborations with innovative, mass spectrometric technology companies, such as BERG in support of proteomic profiling of breast cancer tumors and find ways to improve the diagnostic stratification and treatment of women with breast cancer. Our overall mission in FY17 is to strengthen our capacity to understand, diagnose, and prevent the occurrence of the particularly virulent forms of breast cancer which strike the active duty force disproportionately, thereby affecting military readiness. ***FY 2018 Plans:*** The Breast Cancer CoE will continue to enhance active duty female readiness through study of the increased breast cancer incidence rate in the active duty force by the process of banking biospecimens in the DoD's biorepository, using the repository for intramural/extramural collaborations and secondary usage research. Will continue to develop and improve quality assurance programs and standard operating procedures for the Tissue Bank including conducting biospecimen science research. Will continue to conduct integrative profiling research, for protein-expression based, clinically relevant breast cancer stratification on active case IHC assays of a panel of 20 ImmunoHistoChemical (IHA) biomarker and IHC assays of a panel of 27 biomarkers named Connectivity Map EnHigh Density TMA analysis of biomarkers associated with the development of endocrine resistance. Will conduct breast cancer studies focused on two special patient groups bearing poor outcomes, who are enriched in the military active-duty military population: young women, and African American women. Will conduct breast cancer heterogeneity studies, including cellular heterogeneity of tumor development environment and lineage heterogeneity within one physical cancer tumor. Will conduct studies on mechanistic understanding of breast cancer development from other perspectives, including genetic dispositions, exposure to environmental risks, access to healthcare, and impact of certain life style factors as well as comorbidities. Will conduct breast cancer drug target studies focusing on the triple negative and HER2 subtypes, using 2D and 3D tissue culturing systems and human breast cancer tissues, respectively. Will further develop the informatics infrastructure system to support the evolving needs of Breast Cancer-COE research. Will conduct integrative biomedical data analysis and develop a Breast Cancer Knowledge Base to aid clinical decision-making.			
Accomplishments/Planned Programs Subtotals	0.000	9.900	9.088

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, incorporation into training curriculum throughout the Military Health System and other applicable means.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 378B / *CoE-Breast Cancer Center of Excellence (USU)*

E. Performance Metrics

Performance is judged on the number of active protocols, the number of articles that appear in peer-reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 379A / *CoE-Gynecological Cancer Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	29.041	5.898	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and biologic therapeutics for the management of gynecological disease. The objective of this research is to reduce the incidence, morbidity (illness), and mortality (death) of gynecological diseases among all military beneficiaries.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Gynecological Cancer Center of Excellence (Army)	5.898	0.000	0.000

Description: The Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecological disease.

FY 2016 Accomplishments:

The Gynecological Cancer Center of Excellence conducted both discovery and validation studies of predictive and clinically relevant biomarkers (biological indicators) and molecular targets for the treatment and management of ovarian and endometrial cancers, evaluated the effect of stress intervention on the recurrence of ovarian cancer, worked with the Walter Reed National Military Medical Center Cancer Risk and Prevention Clinic to develop a Clinical Practice Guideline for cancer screening and prevention in patients with hereditary cancer risk syndromes, performed prospective, retrospective, longitudinal and preclinical evaluations of external and host factors as well as biomarker panels to advance early detection, prevention, management and treatment of gynecological malignancies and developed strategies to overcome chemotherapy drug- and radiation-resistance in gynecologic cancer cells. The program sought to understand the initiation of gynecological cancer at its molecular origins by evaluating genes that turn on and off cancer development with a focus on tumor suppressor genes. Additionally the Gynecological Cancer Center of Excellence investigated inhibitors of deoxyribonucleic acid damage response signaling to enhance treatment efficacy of multiple modalities of cancer treatment. The program developed assays for clinical and cancer biomarkers that have diagnostic, prognostic, predictive and therapeutic value. Specific focus was given to biomarkers for early detection as well as for prediction of risk of death, disease progression, treatment resistance, and therapeutic response. The program sought to directly impact clinical care and outcome by furthering laboratory studies of therapeutic peptide vaccines developed in collaboration with the Center of Excellence, as well as clinical trials and window trials evaluating combinations and novel therapeutics in gynecological cancers. Furthermore, chemoprevention efforts focused on development of progestin-Vitamin D combinations and surrogates as well as ways to include metformin and statins in prevention based preclinical studies and prevention trials.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 379A / *CoE-Gynecological Cancer Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Inflammatory cytokines, chemokines as well as tumor-derived and circulating biomarkers were examined in clinical trials and a randomized intervention trial. Robust tissue and data collection continued to support the long-term research goals and objectives of the Gynecological Cancer Center of Excellence. ***FY 2017 Plans:*** No funding programmed. Funding for Breast Cancer Center of Excellence transferred from Army to USUHS (project 379B) starting in FY 2017. ***FY 2018 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	5.898	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, incorporation into training curriculum throughout the Military Health System, and other applicable means.

E. Performance Metrics

Performance of the Gynecological Cancer Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer-reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 379B / *CoE-Gynecological Cancer Center of Excellence (USU)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
379B: *CoE-Gynecological Cancer Center of Excellence (USU)*	0.000	0.000	8.655	7.943	-	7.943	8.987	9.158	9.341	9.528	Continuing	Continuing

Note

The Gynecologic Cancer Center of Excellence (GYN-COE) utilizes a program project type of strategy with overarching objectives to advance knowledge, prevention strategies, companion biomarkers and assays, treatments and interventions across the continuum of care in gynecologic oncology. Our twelve program projects run in parallel rather than in sequence with advances implemented over five years rather than 12 months. Some subprojects target discovery investigations and mechanistic studies whereas others focus on clinical evaluations, population studies and further development leading to deployment. The introduction of new subprojects and maturation of other subprojects allows the GYN-COE to continue to emphasize military and clinical relevance, prioritize bench to bedside translation, and infuse in advances in science, medicine and technology to meet our objectives. This is why the GYN-COE FY17 and FY18 plans are similar.

A. Mission Description and Budget Item Justification

The Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecological disease. The objective of this research is to reduce the incidence, morbidity (illness), and mortality (death) of gynecological diseases among all military beneficiaries.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Gynecological Cancer Center of Excellence	0.000	8.655	7.943

Description: The Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecological disease.

FY 2016 Accomplishments:
No Funding Programmed.

FY 2017 Plans:
The FY 2017 program will build on the foundational elements of investigating gynecological carcinogenesis (the initiation, progression, and metastatic spread of cancer) and drug resistance, developing and deploying clinical biomarkers and assays, and improving clinical care and outcome through evaluations of novel therapeutics, prevention strategies, assessments and interventions in gynecological oncology using pre-clinical studies and clinical trials. These efforts are motivated by bench to bedside translation and clinical application emphasizing early detection, molecular profiling and integrated systems level analysis of gynecological malignancies that will have a major impact on diagnosis, treatment efficacy as well as assessment of prognosis,

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 379B / *CoE-Gynecological Cancer Center of Excellence (USU)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
response to treatment, and disease monitoring. Members of the GYN-COE collaborate in populations-based investigations of risk, outcome, natural history, lifestyle, staging and treatment in gynecological oncology to inform the design, evaluation, analysis, interpretation and ultimate deployment of novel biomarkers, next generation assays, therapeutics, prevention strategies, assessments and interventions in gynecological oncology. Focus will turn to further testing of actionable events and targets in the pathways leading to cancer through both animal modeling with potential for human trials conducted through external partners. Biomarker-based assays for early detection, response to therapy and patient outcome will be tested in robust external data sets to prepare for prospective human testing, and when merited in window trials as well as prospective clinical trials. Utilizing the continually growing Tissue and Data Network with our associated repository and data center with robust clinical, cancer treatment and outcome data, an array of Registries both public and military-centric and our expanded collaborative network of national and internal investigative multidisciplinary team, we will continue to integrate advances in science, technology, medicine, molecular profiling and integrated systems biology and networking to identify, validate and deploy clinical biomarkers, risk scores, and next generation assays for predicting disease, risk and outcome in gynecological cancer patients, preventing disease, ensuring readiness, containing costs, improving clinical care and outcome in ways that promote dignity, quality, efficacy and impact. ***FY 2018 Plans:*** The FY2018 program will continue to identify molecular alterations in gynecologic cancers and develop novel strategies for prevention, early detection, and precision treatment of these diseases. This will be accomplished by investigating ovarian, uterine and cervical carcinogenesis (the initiation, progression, and metastatic spread of cancer) and drug resistance in pre-clinical and clinical biospecimens. We will develop and deploy clinical biomarkers and assays for gynecologic malignancies throughout the spectrum of care and improve clinical care and outcome through evaluation of novel therapeutics, prevention strategies, assessments and interventions in gynecological oncology using pre-clinical studies and clinical trials. We will continue to collaborate in investigations of racial and ethnic disparities, risk, outcome, natural history, lifestyle, staging and treatment in cancer including gynecologic malignancies. Military and civilian biobanks, registries, core facilities, training programs, and multidisciplinary investigations will be used to advance applied proteogenomics and organizational learning, and to ensure readiness, cost containment and improvements in clinical care and outcomes in gynecologic oncology. An overarching goal during this period is to advance patient awareness, education, support and survivorship to improve quality of life, patient experience and mitigate effects. These efforts enhance the experience of care, ensure readiness of the fighting force, and improve beneficiary health adding value while decreasing cost for the Department of Defense.			
Accomplishments/Planned Programs Subtotals	0.000	8.655	7.943

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 379B / *CoE-Gynecological Cancer Center of Excellence (USU)*

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, and into training curriculum throughout the Military Health System, and other applicable means.

E. Performance Metrics

Performance of the Gynecological Cancer Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer-reviewed journals, presentation at national and international meetings, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 381A / *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	11.777	3.255	3.051	2.697	-	2.697	2.914	3.118	3.180	3.244	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Integrative Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), the focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by incorporating biomolecular (pertaining to organic molecules occurring in living organisms) research to detect CVD at an early stage, and identifying markers of increased risk for heart attack in Service members. Using a systems biology outcomes research approach, ICHP characterizes relationships between CVD, other cardio-metabolic disease states and maladaptive lifestyle behavior patterns unique to Service members such as pre-diabetes, stress, obesity and sleep disorders with the aim of targeting these disorders in their pre-clinical phase and achieving ideal/optimal cardiovascular health goals outlined by the American Heart Association. ICHP's ultimate goal is to translate the evidence-based research findings for application into clinical practice in an effort to achieve the following research aims: (1) improve Force Health by better understanding the CVD risk susceptibility of military-specific populations such as Wounded Warriors through leading-edge research using novel tools and technologies, (2) investigate and create transformational models of healthcare delivery through personalized CVD prevention tracks as an adjunct to traditional care, and (3) refine individualized prevention strategies through statistical data modeling to define the most cost-effective and sustainable approaches in promoting cardiovascular health throughout the military lifecycle.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Integrative Cardiac Health Center of Excellence (Army)	3.255	3.051	2.697
Description: The focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by combining bimolecular research with lifestyle change strategies to detect CVD at an early stage, and identifying markers of increased risk for heart attack in Service members.			
FY 2016 Accomplishments: For the Integrative Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), the focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by incorporating biomolecular (pertaining to organic molecules occurring in living organisms) research to detect CVD at an early stage, and identifying markers of increased risk for heart attack in Service members. Using a systems biology outcomes research approach, ICHP characterizes relationships between CVD, other cardio-metabolic disease states and maladaptive lifestyle behavior patterns unique to Service members such as pre-diabetes, stress, obesity and sleep disorders with the aim of targeting these disorders in their pre-clinical phase and achieving ideal/optimal cardiovascular health goals outlined by the American Heart Association. ICHP's ultimate goal is to translate the evidence-based research findings for application into clinical practice in an effort to achieve the following research aims: (1) improve Force Health by better understanding the CVD risk susceptibility of military-specific populations such as Wounded Warriors through leading-edge research using novel tools and			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 381A / *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
technologies, (2) investigate and create transformational models of healthcare delivery through personalized CVD prevention tracks as an adjunct to traditional care, and (3) refine individualized prevention strategies through statistical data modeling to define the most cost-effective and sustainable approaches in promoting cardiovascular health throughout the military lifecycle. ***FY 2017 Plans:*** The ICHP impacts clinical practice guidelines by developing clinical decision support tools and new models for cardiovascular and overall health; conducts research studies to improve the health of the Active Duty force by investigating the effectiveness of personalized (gender specific) lifestyle change interventions specifically designed for the military and the effects of these interventions on preclinical atherosclerosis. ICHP continues recruitment in the study to investigate the effects of lifestyle intervention on vascular function in Active Duty Service members with high lifetime CVD risk but who currently do not have clinical heart disease. ICHP is improving the precision of cardiovascular disease risk assessment and detection by exploring novel biomolecular markers and tests as indicators for early disease. ICHP is collaborating with the Mayo Clinic and Cleveland Clinic for these efforts. ICHP is using this information to tailor personalized health interventions and build resiliency in the military population before disease affects quality of life. The Wounded Warriors project is exploring cardiovascular risk in the amputee and injured Warfighter, examining novel biomolecular markers designed to significantly advance the precision of risk detection to better tailor health interventions and begin preliminary analysis. ***FY 2018 Plans:*** The ICHP will influence clinical practice guidelines by developing clinical decision support tools and new models for cardiovascular and overall health; will conduct research studies to improve the health of the Active Duty force by investigating the effectiveness of personalized (gender specific) lifestyle change interventions specifically designed for the military and the effects of these interventions on preclinical atherosclerosis. ICHP will continue recruitment in the study to investigate the effects of lifestyle intervention to improve cardiovascular health and reduce cardiovascular disease risk in AD Service members and beneficiaries especially targeting the population that are presumably fit but still vulnerable for sudden cardiac death and heart attacks. ICHP will initiate a precision medicine effort that will explore novel biomolecular markers and tests as indicators for early (preclinical) cardiovascular disease risk assessment, and discover and characterize new clinical phenotypes, detect cardiovascular disease in early stages when it is more likely to be reversible. ICHP will collaborate with Walter Reed Bethesda Cardiovascular Service, the Mayo Clinic, Abbott Laboratories, and Integrative Systems Biology for these efforts. ICHP will use this information to tailor personalized health interventions and build resiliency in the military population before disease affects quality of life. ICHP will collaborate with the Department of Psychology within the Uniformed Services University of Health Sciences to evaluate the benefits of ICHP Cognitive Behavioral Therapy intervention to relieve insomnia. The Wounded Warriors project will explore cardiovascular risk in the amputee and injured Warfighter to include the collection of bio-samples for novel biomolecular markers designed to significantly advance the precision of risk detection to better tailor health interventions.			
Accomplishments/Planned Programs Subtotals	3.255	3.051	2.697

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 381A / *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer reviewed journals, revised clinical practice guidelines, and training of residents and fellows in the Military Health System

E. Performance Metrics

Integrative Cardiac Health Care Center of Excellence performance is judged on high impact discoveries, development of new diagnostic and treatment strategies, identification of emerging issues of disease feature and patterns, the amount of extramural funding received, the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of medical students, residents and post-doctoral fellows in the Military Health System.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 382A / *CoE-Pain Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
382A: *CoE-Pain Center of Excellence (Army)*	6.436	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Pain Center of Excellence (Army) examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration. The Pain Center of Excellence is an integral part of the Defense and Veterans Center for Integrative Pain Management whose mission is to become a referral center that supports world-class clinical pain services, provides education on all aspects of pain management, coordinates and conducts Institutional Review Board-approved clinical research and Institutional Animal Care and Use Committee-approved basic laboratory and translational pain research, and serves as the advisory organization for developing enterprise-wide pain policy for the Military Health System. In FY 2015, the Pain CoE funding line is transferred from Army to USUHS.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Pain Center of Excellence (Army)	0.000	0.000	0.000
Description: The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration. ***FY 2016 Accomplishments:*** No funding programmed. Funding transferred to USUHS. ***FY 2017 Plans:*** No funding programmed. ***FY 2018 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 382A / *CoE-Pain Center of Excellence (Army)*

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, incorporation into training curriculum throughout the Military Health System, and other applicable means.

E. Performance Metrics

Performance by the Pain Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 382B / *CoE-Pain Center of Excellence (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
382B: *CoE-Pain Center of Excellence (USUHS)*	2.484	2.610	2.641	2.822	-	2.822	3.310	3.376	3.445	3.514	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration. The Pain Center of Excellence is an integral part of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) whose mission is to become a referral center that supports world-class clinical pain services, provides education on all aspects of pain management, coordinates and conducts Institutional Review Board-approved clinical research and Institutional Animal Care and Use Committee-approved basic laboratory and translational pain research, and serves as the advisory organization for developing enterprise-wide pain policy for the Military Health System. In FY 2015, management of the Pain CoE was transferred from Army to USUHS.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Pain Center of Excellence (USUHS)	2.610	2.641	2.822

Description: The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and its impact on rehabilitation and recovery.

FY 2016 Accomplishments:

The DVCIPM made significant progress toward the 5-year plan for FY15-19 that focuses on further developing the Pain Assessment Screening Tool and Outcomes Registry (PASTOR); complementary and integrative pain management (CIPM) through clinical assimilation studies of modalities and interventional technologies for improved pain management. DVCIPM also had many accomplishments as the MHS's coordinating organization for pain education and clinical policy development. Progress this year includes approval of two protocols: Study 1: "Characterization of Postoperative Pain in Total Knee and Hip Arthroplasty and Assessment of the Defense and Veterans Pain Rating Scale for Persistent Post-Surgical Pain"; and Study 2: "Characterizing the Biopsychosocial Impact on Caregivers in Patients Undergoing Joint Replacement and Cervical/Lumbar Spine Surgery: A Pilot Study". We also expect to complete the DVPRS Pilot Introduction at 3 MHS Medical Treatment Facilities; analysis of "Characterization of Postoperative Pain in Total Knee and Hip Arthroplasty and Assessment of the Defense and Veterans Pain Rating Scale for Persistent Post-surgical Pain"; facilitate the MHS Opioid Safety Strategy; Federal Medicine Mandatory Prescribing Training; MHS Pain Campaign; and finalize MOU's with States of West Virginia, Virginia and Duke University. Additionally, we are working with USU CNRM about building/housing DVCIPM Biobank and establishing a scientific/ programmatic oversight board.

FY 2017 Plans:

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 382B / *CoE-Pain Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
The DVCIPM has developed a 5-year plan for FY15-19 that will focus on further developing the Pain Assessment Screening Tool and Outcomes Registry (PASTOR); to include developing a pain registry biobank, establishing a research database; and utilizing predictive modeling to assist providers with pain management decision-making. DVCIPM will continue to focus on complementary and integrative pain management (CIPM) through clinical assimilation studies of modalities such as; battlefield acupuncture (BFA), yoga and massage; evaluation of novel analgesics; and interventional technologies for improved pain management. ***FY 2018 Plans:*** The DVCIPM will continue to focus on further building and streamlining the Pain Assessment Screening Tool and Outcomes Registry (PASTOR)and apply for grants for data analysis. DVCIPM will continue to focus on complementary and integrative pain management (CIPM) through clinical assimilation studies of modalities such as: battlefield acupuncture (BFA); yoga and massage; evaluation of novel analgesics; and interventional technologies for improved pain management. Pain education and policy development will continue to be a primary theme.			
Accomplishments/Planned Programs Subtotals	2.610	2.641	2.822

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, incorporation into training curriculum throughout the Military Health System, and other applicable means.

E. Performance Metrics

Performance by the Pain Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	27.590	5.789	7.900	7.250	-	7.250	8.203	8.359	8.526	8.696	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Center for Prostate Disease Research (CPDR) is an interdisciplinary translational cancer research program of the Department of Surgery, Uniformed Services University of the Health Sciences (USU), the Walter Reed National Military Medical Center (WRNMMC), the Murtha Cancer Center, and the Urology Service at WRNMMC. The CPDR conducts state-of-the-art clinical and translational research with emphasis on precision medicine to enhance the readiness of active duty personnel juxtaposed with the continuum of medical care for military retirees and beneficiaries. The CPDR enriches the training of the next generation of physicians/ scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system. Ground-breaking discoveries through strong academic and clinical research; e.g., over 24 yrs. and 450 publications) have led to major advances in translational prostate cancer research and treatment. The CPDR integrates expertise of urologic and medical oncologists, cancer biologists, genitourinary pathologists, epidemiologists, bio-statisticians, medical technologists, research nurses, patient educators, bioinformaticians, and program management specialists. All these areas of expertise provide state-of-the-art resources for in-house and collaborative research in prostate cancer. The program is also committed to translational research training for future generations of physicians and scientists at leading DoD medical institutions (USU, WRNMMC, JPC, NMCSD, MAMC, SAMMC, and TAMC).

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: CoE-Prostate Cancer Center of Excellence (USUHS)	5.789	7.900	7.250
Description: The CPDR is at the forefront of "cutting-edge" clinical, basic science and epidemiologic research. The emphasis is on improving diagnosis, prognosis and treatment of prostate cancer involving new modalities such as MRI guided biopsy, gene-based biomarkers, and precision medicine strategies targeting causal gene alterations in prostate cancer. The CPDR multi-center database is a unique programmatic resource, enrolling over 27,500 DoD health care beneficiaries under suspicion for prostate cancer, with longitudinal follow up to 23 years. This database continues to highlight emerging issues in prostate cancer management such e.g., treatment outcomes, racial/ethnic differences, quality of life and discovery of novel molecular prognostic markers. In light of current issues related to overtreatment of early detected prostate cancers and poorly understood biology of prostate cancer, CPDR's long-term biospecimen banks, high-impact discoveries and collaborations are leading towards better diagnostic and prognostic molecular markers and therapeutic targets with promise in improving the management of the disease. The CPDR's health disparity research focus has uniquely benefited from studying a prostate cancer patient cohort, with a high representation of African American men, in an equal-access military health care system. Ground-breaking studies of the most validated prostate cancer gene, ERG, in over 1,500+ patients provide the first definitive information on prostate cancer biology underscoring racial/ethnic differences with potential to enhance personalized medicine. The CPDR's state-of-the-art research infrastructure and framework is providing education and training for over 100 next generation physicians, scientists, medical and graduate students within DoD medical institutions.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018

FY 2016 Accomplishments:

Precision Medicine Research Focus:

• Streamlined the first MRI-ultrasound fusion image guided biopsy technology in a DoD medical center (at WRNMMC, Bethesda) in enhancing detection of clinically significant prostate cancers.

• To address the urgent need in forecasting outcomes for patients with early-detected prostate cancer, CPDR completed the second validation of a biopsy-based, 17-gene panel prognostic assay (Oncotype DX® Prostate Cancer Test). In the racially diverse cohort of DoD patients, this test demonstrated similar performance in predicting adverse pathology and cancer progression (Genomic Health Inc. /USU-HJF CRADA; Cullen et al., European Urol, 2015; Brand et al., Urology, 2016).

• To overcome limitations of currently used serum PSA test and to improve diagnostic assays, CPDR has completed the first multi-omics study (proteome, lipidome and metabolome) using 700 serum specimens from CPDR biospecimen bank. A twelve analyte diagnostic panel has been identified and is now under further validation (Berg Pharma/ USU-HJF CRADA, U.S. Patent Application, 2016).

• Toward improving the prostate cancer treatment decision-making process, a new study was completed examining factors that influence decision-making among DoD patients who participated in the CPDR WRNMMC multidisciplinary clinic (Hurwitz et al., Urol Oncol, 2016).

• A prospective quality of life (QoL) outcomes study was completed that examined patients choosing active surveillance compared to those biopsied but not diagnosed with prostate cancer to better understand the impact of cancer diagnosis and factors that might improve QoL in such patients (Pham et al., J Urol, 2016).

Health Disparity Research:

• First insights into the prostate cancer genomes were developed establishing significant differences of the two main prostate cancer driver genes (ERG and PTEN) between African American and Caucasian men and new discoveries highlighting genes (LSAMP, CHD1) enriched in African American prostate cancers (Petrovics et al., EBioMedicine 2015, and CRADA with Harvard Medical School). These findings led to the development of ethnicity-informed biomarker panels towards enhancing the diagnosis and prognosis of prostate cancer (two U.S. Patent Applications 2016).

• Completed a meta-analysis of world-wide assessment of the most common prostate cancer driver gene ERG, revealing striking differences in ERG frequencies between races and geographic regions (Sedarsky et al Nature Reviews Urology 2016).

• Completed a definitive study of ERG oncoprotein (nearly 1,000 patients, including the largest cohort of African American patients) highlighting novel prognostic features of ERG-based stratification of prostate cancer (Cullen et al., European Urology Focus, 2016).

• A recently completed study of BRCA1 and BRCA2 germline mutations provided new insights into the higher frequency of BRCA2 mutations in African American patients and overall association with aggressive prostate cancer (Petrovics et al., American Urologic Association (AUA) Annual Meeting, 2016, selected for AUA highlights and press release within the top 3% of presentations of 2,800 at AUA 2016).

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Development of Molecular Diagnostic and Prognostic Tools: • Towards developing broadly applicable diagnostic biomarker panels, CPDR defined a gene expression signature in tissue-based assays (DLX1, NKX2.3, COL10A1, PSGR, HOXC6 and HOXC4) demonstrating similar performance in distinguishing tumors from normal tissues in African American and Caucasian American patients (NCI/EDRN Meeting, Bethesda 2016, Patent Application 2016). • A tissue-based prognostic gene panel has been identified using NanoString platform to differentiate between indolent and aggressive prostate cancer with further validation under way (AUA 2016; AACR 2016). • CPDR has developed initial strategies for assessing serum autoantibodies towards developing diagnostic and prognostic markers (Rastogi et al., Oncotarget, in review, 2016). • In collaboration with the Pacific Northwest National Laboratory mass spectrometry based novel protein biomarker assays in prostate tissues and urine have been developed which are under further evaluations (HUPO 2016). Novel Strategies for Stratification and Treatment of Prostate Cancers: • State-of-the-art clinical trials are being assessed for the treatment of metastatic prostate cancers: Radium-223; the PARP inhibitor Rucaparib; and immunotherapies: Provenge, Leuvectin, ProstAtac and Prostvac. • Developed novel concepts in facilitating degradation of androgen receptor, a central player in development of castration resistant prostate cancer. CPDR continues defining the mechanistic role of PMEPA1 in androgen receptor regulation by in vitro and in vivo transgenic mouse models (AUA 2016; AACR 2016). • Validated a tissue based androgen receptor functional readout for therapeutic stratification of prostate cancers enhancing early decisions in hormonal therapy. • An estimated five million prostate cancer patients world-wide harbor the ERG oncogene, making it one of the most common oncologic targets. Thus, therapeutic targeting of ERG is a current CPDR focus towards prostate cancer precision medicine. CPDR has completed the preclinical assessment of the selective small molecule inhibitor of ERG, ERGi-USU and its new derivatives in cell culture and xenograft models of prostate cancer (Mohamed et al., AACR and AUA 2016; US Patent Application, 2016). • Discovered a biological mechanism for early events in prostate cancer development highlighting the interface of male hormone receptor and the common oncogenic pathway (ERG) with potential in defining novel therapeutic targets (Sreenath et al., AUA, AACR, 2016). The CPDR Education and Training program: • In 2016, three urology residents from WRNMMC, six USUHS medical school students including Capstone Program awardees, one graduate student from USUHS completed or continue to receive training at CPDR. Further, the Education and Training program continued to train five post-doctoral fellows and ten summer interns.			
FY 2017 Plans: Precision Medicine Focus:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
• Continue to address the utility of MRI-ultrasound fusion image technology for improving diagnosis of clinically significant cancers. Initiate the molecular characterization of MRI-ultrasound fusion image guided biopsy specimens for prognostic evaluation (collaboration with NCI). • Support new national cancer precision medicine initiatives e.g., Cancer Moonshot under the Murtha Cancer Center. • Leverage the large, longitudinal DoD cohort of racially diverse prostate cancer patients to develop and validate prediction models for disease progression, quality of life, and overall survival across the spectrum of cancer treatments, as well as identify factors that predict definitive treatment for patients initially managed on active surveillance. • Develop data on military-specific exposures in prostate cancer onset and progression, assessing the role of predisposing conditions (e.g., environmental and genetic) for service members. • Validate the integrated omics study for diagnostic and prognostic biomarker discovery towards overcoming limitations of currently used serum PSA diagnostic test in collaboration with Berg Pharma. • Enhance the collaborative validation study of the Oncotype DX Prostate Cancer prognostic panel focusing on metastatic prostate cancer. Health Disparity Research: • Leverage CPDR's lead towards identification of genes that will enhance diagnosis, prognosis and treatment of racially diverse prostate cancer patients in MHS: Develop synergy with USU, The American Genome Center to perform whole-genome and whole-transcriptome sequencing on a large CPDR cohort of African American and Caucasian American patients with defined clinical attributes (patients with aggressive disease progression versus indolent disease). • Develop new molecular strategies for monitoring and treatment of aggressive disease in African American patients, e.g., validate the CPDR original discovery of LSAMP deletion in a larger patient cohort. • Enhance existing and develop new experimental models focusing on cancer driver genes (ERG, LSAMP, PCGEM1 and similar genes) prevalent in African American patients for innovating novel therapeutic strategies. • Further develop the collaborative study with NCI investigators highlighting higher frequency of BRCA2 germ line mutations in prostate cancers of African American patients and overall association of BRCA2 with advanced disease. Development of Molecular Diagnostic and Prognostic Tools: • Enhance and leverage the unique DoD prostate cancer research resources integration of clinical, biospecimen and molecular databases through advanced informatics platforms to enhance development of diagnostic and prognostic tools of prostate cancer. Develop new strategies for specimen processing for proteomics and liquid biopsies. • Continue to enhance the prognostic utility of the CPDR-ERG monoclonal antibody in the context of ethnicity and co-morbidities. • Leverage the discovery of prognostic biomarker candidates from whole-genome and whole-transcriptome analyses for defining an ethnicity-informed prognostic panel for prostate cancer. • Leverage the evaluation of CPDR gene panels in urine exosomes in clinical trial and collaboration with the Exosome Diagnostics Inc. • Confirm the diagnostic/prognostic potential of prostate cancer-specific serum auto-antibodies in independent cohorts.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Novel Strategies for Stratification and Treatment of Prostate Cancers: • Continue to develop clinical trials for the treatment of metastatic prostate cancers: Radium-223; the PARP inhibitor Rucaparib; and immunotherapies: Provenge, Leuvectin, ProstAtac and Prostvac. • Develop studies focusing on evaluation of immuno-biomarker panels for the assessment of tumor infiltrating cells and their utility in prostate cancer prognosis and response to immunotherapy in collaboration with NCI/NIH. • Accelerate the pre-clinical development of the novel therapeutic inhibitors of new USU-ERGi derivatives, high-throughput screen and X-ray crystal structure based small molecule ERG inhibitors towards the treatment of early detected prostate cancer with promise for a paradigm shift in new generation of prostate cancer therapeutics. • Enhance utilization of in vivo prostate cancer transgenic and tumorigenicity models for the evaluation of emerging small molecule inhibitors, such as new ERGi-USU derivatives, small molecule inhibitors of ERG, PMEPA1 peptidomimetic targeting AR degradation and other key prostate cancer driver gene defects. • Develop novel concepts, e.g., targeting the androgen receptor modulator, PMEPA1 gene in facilitating degradation of androgen receptor, a central player in development of castration resistant prostate cancer. • Continue evaluating the CPDR androgen receptor function index (ARFI) gene panel to enhance new paradigms for earlier and more effective stratification of patients for androgen axis targeting drugs, such as Enzalutamide and Arbiraterone Acetate. • Enhance the CPDR's original discovery of new types of non-protein coding genes, e.g., PCGEM1, in the activation of androgen receptor with potential application in androgen-network targeted therapeutic stratification. Education and Training Program: • Continue investing in the training of next generation of DoD physicians and researchers. Leverage the strong track record in translational research training for medical researchers at DoD institutions, e.g., WRNMMC urology residents, USU Capstone medical and graduate students. • Nurture the trainees (urology residents, post-doctoral fellows, graduate students and research staff) through invited lectures from leading experts in prostate cancer field.			
FY 2018 Plans: Precision Medicine Focus: • Refine and develop modalities for diagnosing and prognosing clinically significant cancers prostate cancers. Build on the molecular/clinico-pathologic prognostic signatures of MRI-ultrasound fusion image guided biopsy specimens. • Enhance the support for national cancer precision medicine initiatives e.g., Cancer Moonshot under the Murtha Cancer Center. Build on APOLLO projects initial experience on proteogenomics signatures. • Continue to leverage the large, longitudinal DoD cohort of racially diverse prostate cancer patients to develop and validate prediction models for disease progression, quality of life, and overall survival across the spectrum of cancer treatments, as well as identify factors that predict definitive treatment for patients initially managed on active surveillance.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
• Build on data that will lead to military-specific exposures in prostate cancer onset and progression assessing the role of predisposing conditions (e.g., environmental and genetic) to service members. • Deploy multi-center validation of the diagnostic and prognostic biomarker panels from integrated omics study addressing the limitations of currently used serum PSA diagnostic test (collaboration with Berg Pharma). Health Disparity Research: • Continue to leverage CPDR's lead towards identification of genes that will enhance diagnosis, prognosis and treatment of racially diverse prostate cancer patients in MHS: Develop synergy with USU, The American Genome Center to perform whole-genome and whole-transcriptome sequencing on a large CPDR cohort of African American and Caucasian American patients with defined clinical attributes (patients with aggressive disease progression versus indolent disease). • Lead the research delineating the comprehensive molecular taxonomy of under studied prostate cancer genomes (African American and Asians) towards enhancing diagnosis, prognosis and treatment broadly applicable to the US population. • Continue to enhance experimental models focusing on prostate cancer driver genes prevalent for innovating novel therapeutic strategies. • Enhance collaborations with NCI investigators on genetic predisposition for metastatic prostate cancer. Development of Molecular Diagnostic and Prognostic Tools: • Continue to enhance and leverage the unique DoD prostate cancer research resources integration of clinical, biospecimen and molecular databases through advanced informatics platforms to enhance development of diagnostic and prognostic tools. • Continue to enhance the prognostic utility of the CPDR-ERG monoclonal antibody in the context of ethnicity and co-morbidities. • Develop and validate gene-based broadly applicable diagnostic and prognostic biomarkers in multi-center setting, e.g., evaluation of CPDR gene panels in urine exosomes in clinical trial and collaboration with the Exosome Diagnostics Inc. • Expand the research on serum and tissue based omics-defined biomarkers (mass spectrometry-based, serum antigen- and autoantibody-based detections). Novel Strategies for Stratification and Treatment of Prostate Cancers: • Continue to employ state-of-the-art clinical trials for the treatment of metastatic prostate cancers and develop new trials targeting prostate cancer driver genes, e.g., ERG. • Develop studies focusing on enhancing immunotherapy of prostate cancer. • Complete comprehensive evaluations of ERGi to support Phase I clinical trial. • Enhance biological understanding of less understood prostate cancer driver genes through cell culture based and engineered mouse models and tumorigenicity models for developing novel therapeutics. • Develop novel concepts, e.g., targeting the androgen receptor modulator, PMEPA1 gene in facilitating degradation of androgen receptor, a central player in development of castration resistant prostate cancer. • Develop multi-center evaluation of the CPDR androgen receptor function index (ARFI) gene panel towards earlier and more effective stratification of patients for androgen axis targeting drugs. Education and Training Program:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
• Continue investing in the training of next generation of DoD physicians and researchers. Leverage the strong track record in translational research training for medical researchers at DoD institutions, e.g., WRNMMC urology residents, post-doctoral fellows, USU Capstone medical and graduate students.			
Accomplishments/Planned Programs Subtotals	5.789	7.900	7.250

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Prostate Cancer Center of Excellence: Performance is judged on high impact discoveries, development of new diagnostic and treatment strategies, identification of emerging issues of disease feature and patterns, the amount of extramural funding received, the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of medical students, residents and post-doctoral fellows in the Military Health System.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 398A / *CoE-Neuroscience Center of Excellence (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
398A: *CoE-Neuroscience Center of Excellence (USUHS)*	3.679	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

Note

The Center for Excellence in Neuroscience Project is closed. All future projects will be supported by This project was consumed under the Center for Neuroscience and Regenerative Medicine (CNRM).

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USUHS), the Military Clinical Neuroscience Center of Excellence (MCNCoE), formerly a Congressional Special Interest program, was chartered in 2002 to conduct basic, clinical, and translational research studies of militarily relevant neurological disorders affecting U.S. service members and military beneficiaries. The Center's mission is to improve prevention, diagnosis, and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions. The MCNCoE goals include supporting neuroscience education and research endeavors at military treatment facilities across the DOD healthcare system and facilitating a network of collaborations between investigators across these facilities.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: CoE-Neuroscience Center of Excellence (USUHS) ***Description:*** The Military Clinical Neuroscience Center of Excellence (MCNCoE) is to improve prevention, diagnosis, and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions. The MCNCoE's approach to its goals includes supporting the research potential of military treatment facilities across the DOD system as well as the national capital area, and facilitating a network of collaborations between investigators across these facilities. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.	0.000	0.000	-
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 398A / *CoE-Neuroscience Center of Excellence (USUHS)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 429A / *Hard Body Armor Testing (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
429A: *Hard Body Armor Testing (Army)*	1.356	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

The Hard Body Armor project plans to develop a surface-mounted sensor system that will add critical dynamic data to the current clay test procedure and develops human skull fracture injury criteria for focused blunt impacts to the human head. This research develops and validates a method for assessing body armor performance against blunt trauma and will be fully compatible with the current testing method. The adoption of armor and helmet design standards that estimate injury type and severity based on biomechanics will allow designers to rationally create armor and helmets that protect each body region and allow the development of standards based on true protection outcomes.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Hard Body Armor	0.000	0.000	0.000
Description: Develop a surface-mounted sensor system that will add critical dynamic data to the current clay test procedure and develops human skull fracture injury criteria for focused blunt impacts to the human head. ***FY 2016 Accomplishments:*** No funding programmed. ***FY 2017 Plans:*** No funding programmed. ***FY 2018 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Disseminate to the DoD testing community an improved biofidelic blast test manikin (model with characteristics that mimic pertinent human physical ones such as size, shape, mass)that includes the capability to measure and predict skeletal occupant injury during under body blast events in combat and transport vehicles involving a landmine or improvised explosive device.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 429A / *Hard Body Armor Testing (Army)*

E. Performance Metrics

Principal investigators will participate in In-Progress Reviews, DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and/or are subjected to Program Sponsor Representative progress review to ensure that milestones are being met and deliverables will be transitioned on schedule.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 431A / *Underbody Blast Testing (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
431A: *Underbody Blast Testing (Army)*	36.264	2.478	1.869	8.000	-	8.000	10.800	9.200	1.400	0.000	-	-

A. Mission Description and Budget Item Justification

To better protect mounted warriors from the effects of underbody blast (UBB) caused by landmines or Improvised Explosive Devices (IEDs), UBB Testing medical research project will provide new data on the biomechanics of human skeletal response that occurs in an attack on a ground combat vehicle. The data will provide a biomedical basis for the development of a Warrior-representative blast test manikin (the Warrior Injury Assessment Manikin or WIAMan project) and the required biomedically-valid injury criteria that can be used in Title 10 Live Fire Test and Evaluation (LFT&E) to characterize dynamic events, the risk of injury to mounted warriors, and to support acquisition decisions. This new data will also benefit the overall DoD effort in vehicle and protection technology for the UBB threat. This work is needed to overcome the limitations of the current test manikin and injury criteria which were designed for the civilian automotive industry for frontal crash testing and as such are not adequate in the combat environment. The current manikins do not represent the modern Warrior and were not designed for the vertical acceleration environment associated with UBB events. Consequently, current LFT&E crew survivability assessment methodologies are limited in their ability to predict the types and severity of injuries seen in these events. Due to this technology gap, military ground vehicles are being fielded without fully defined levels of injury risk and crew survivability for UBB events. The data produced by this project will be used to satisfy a critical need for a scientifically valid capability for analyzing the risk of injury caused by UBB.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Underbody Blast Testing	2.478	1.869	8.000
Description: Testing will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or IED, and the biomedical basis for the development of a Warrior-representative blast test manikin and associated biomedically-validated injury criteria that can be used to characterize dynamic events and injury risks for LFT&E crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats.			
FY 2016 Accomplishments: The Underbody Blast Testing project continued medical research in the areas initiated in FY 2015 but with the emphasis shifting to perform matched pair testing of the first generation WIAMan prototype. This enabled a pairwise comparison between the human injury probability curves and the responsiveness of the WIAMan first generation prototype in the military and underbody blast environments. This work informed the development of whole-body and component injury criteria and the protective technology for use in the underbody blast environment. Started laboratory testing to determine differences in male and female mechanical response in the underbody blast environment.			
FY 2017 Plans: FY17 plans are to continue to develop body region specific injury criteria under blast loading using whole body dynamic data from whole body blast tests. The project will test various hypotheses to determine how to create the first injury (i.e., fracture)			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 431A / *Underbody Blast Testing (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
and subsequent severe injuries (i.e., complex fractures). The goal is to predict injury with enough resolution to make decisions between competing protective equipment. Using supported hypotheses from preliminary component testing in finalized tests to generate and update human injury probability (dose-response) curves and injury assessment response curves (cadaver - ATD relationship). In addition, it will generate male and female post mortem human subjects injury tolerance differences to determine the need for a female-specific manikin. ***FY 2018 Plans:*** Biofidelity response corridors that have been completed will be used to validate second generation prototypes of the WIAMan. Human injury assessment curves will continue to be developed for the lower extremities, pelvis and spine from laboratory testing that created thresholds of cadaveric fractures and subsequent severe injuries (i.e., complex fractures). Laboratory testing to generate female post mortem human subject injury tolerances will continue and will inform the analysis of alternatives for developing a female specific manikin.			
Accomplishments/Planned Programs Subtotals	2.478	1.869	8.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Produce BRC and human injury probability curves for human skeletal response and tolerance in the military UBB environment and transition them to the Program Execution Office for Simulation, Training and Instrumentation for use in the development of the WIAMan UBB test manikin and for general use in the research, development, test and evaluation community. Develop injury assessment reference curves for use with WIAMan manikin to support vehicle and protection technology acquisition decisions.

E. Performance Metrics

PIs will participate in In-Progress Reviews, technical interchange meetings, and theater injury analysis reviews. PIs will publish emerging results in the Proceedings of Injury Biomechanics Symposia and in relevant journals. As required, PIs will participate in DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and are subjected to periodic progress reviews to ensure that milestones are being met and deliverables will be transitioned on schedule. An external peer review of the medical research will be conducted to ensure the medical research is scientifically valid and suitable for accreditation for use in supporting acquisition decisions.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 448A / *Military HIV Research Program (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
448A: *Military HIV Research Program (Army)*	11.933	6.093	6.070	6.359	-	6.359	7.360	7.877	8.035	8.196	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project funds research to develop candidate Human Immunodeficiency Virus (HIV) vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. All HIV technology development is conducted in compliance with U.S. Food and Drug Administration (FDA) regulations. Evaluations in human subjects are conducted to demonstrate safety and effectiveness of candidate vaccines, as required by FDA regulation. Studies are conducted stepwise: first, to prove safety; second, to demonstrate the desired effectiveness of the vaccine in a small study (to demonstrate early proof-of-concept); and third, to demonstrate effectiveness in large, diverse human population clinical trials. All results are submitted to the FDA for evaluation to ultimately obtain approval (licensure) for medical use. This project supports studies for effectiveness testing on small study groups after which they transition to advanced developers for completion of effectiveness testing in larger populations. This program is jointly managed through an Interagency Agreement between the U.S. Army Medical Research and Materiel Command and the National Institute of Allergy and Infectious Diseases. This project contains no duplication with any effort within the Military Departments or other government organizations. The cited work is also consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Military HIV Research Program	6.093	6.070	6.359
Description: The Military HIV Research Program aims to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. In addition, program also aims to develop other prevention and treatment strategies to mitigate the HIV epidemic globally. This project down-selects one or more vaccine candidates that are optimized through pre-clinical studies in non-human primates and conducts human clinical trials in Africa, Asia and the U.S. to test for safety and immunogenicity (ability to invoke an immune response), and early proof of concept efficacy testing.			
FY 2016 Accomplishments: FY16 accomplishments include completion of large scale production and characterization of selected vaccine candidates and initiation of large scale safety and effectiveness trials with one or more vaccine candidates either as single vaccine or combination of several sub-types representing major worldwide distribution.			
FY 2017 Plans: FY17 plans to include performing an Early Capture HIV Cohort study in Uganda, Kenya and Tanzania with the purpose of characterizing recruitment, retention, HIV prevalence, HIV incidence and biological characteristics of acute HIV infection in high-			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 448A / *Military HIV Research Program (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
risk volunteers. This project will also initiate a human population study that will provide knowledge about the earliest HIV events to provide possible clues in developing preventive and/or therapeutic vaccines with the best combination of products. ***FY 2018 Plans:*** In FY18, plans are to extend an Early Capture HIV Cohort studies in Europe and Asia with the purpose of characterizing recruitment, retention, HIV prevalence, HIV incidence and biological characteristics of acute HIV infection in high-risk volunteers and extend human population studies to Asia, Europe and West Africa that will provide knowledge about the earliest HIV events to provide possible clues in developing preventive and/or therapeutic vaccines with the best combination of candidates of interest. This project will conduct human clinical trials in Europe, Africa, Asia and the US to test for safety and immunogenicity, and early proof of concept efficacy testing with selected vaccine candidates that have shown efficacy in non-human primate model.			
Accomplishments/Planned Programs Subtotals	6.093	6.070	6.359

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Mature and demonstrate candidate HIV vaccines, prepare and conduct human clinical studies to assess safety and effectiveness of candidate HIV vaccines. All HIV technology development activities will be conducted in compliance with FDA regulations. Best selected candidates will be transitioned to advanced development through Milestone B.

E. Performance Metrics

Performance of the HIV research program will be monitored and evaluated through an external peer review process, with periodic reviews by the HIV Program Steering Committee and the Military Infectious Diseases Research Program Integrating Integrated Product Team, and in-process reviews.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 830A / *Deployed Warfighter Protection (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
830A: *Deployed Warfighter Protection (Army)*	18.382	4.908	4.889	5.123	-	5.123	5.930	6.345	6.473	6.601	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Armed Forces Pest Management Board (AFPMB), the Deployed Warfighter Protection program plans to develop new or improved protection for military personnel from disease-carrying insect and tick vectors of disease pathogens. The focus of this program is to develop new or improved systems for controlling insects and other biting arthropods that transmit malaria, dengue, chikungunya, Zika virus and other emerging infectious disease pathogens under austere, remote, and combat conditions; understand the physiology of insecticidal activity to develop new compounds with greater specific activity and/or higher user acceptability; examine existing area repellents for efficacy and develop new spatially effective repellent systems useful in military situations; develop new methods or formulations for treating cloth to prevent vector biting; and expand the number of active ingredients and formulations of public health pest pesticides, products and application technologies available for safe and effective applications. The AFPMB partners with the US Department of Agriculture, President's Malaria Initiative and the World Health Organization to lead the development of new management tools against insect vectors that transmit pathogens and against other pest species that can negatively impact military operations at home and abroad.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Deployed Warfighter Protection	4.908	4.889	5.123
Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects.			
FY 2016 Accomplishments: In FY 2016, the Deployed Warfighter Protection (DWFP) program developed tools that enabled deployed forces to better protect themselves and control biting insects, primarily mosquitoes and sand flies, which transmit force degrading disease pathogens. This was accomplished through research, testing and evaluation of products, patent submissions, licensing, and U.S. Environmental Protection Agency (EPA) registrations for new insecticides. The DWFP maintained its focus on personal protection systems, new insecticides, and vector control/insecticide application technologies. For enhanced personal protection systems, protective clothing efforts were reviewed pending results of the FY 2015 evaluations of prototype bite proof fabric for commercialization; efficacy testing of the alternative to permethrin for treating combat uniforms was initiated and an application for EPA registration was initiated. Within this same focus area, under area/spatial repellents, the DWFP program expanded field tests focused on the best performing area/spatial-repellent dispensers evaluated in FY 2015 and worked with the EPA and associated industry partner to pursue EPA registration for military use. For new insecticides, the DWFP program down-selected top performing, novel molecular pesticides tested in FY 2015 for expanded field testing; conducted faster, more efficient, laboratory screening of potential plant-derived and synthetic insecticides to identify promising candidate compounds; and executed field evaluations of insecticides identified in FY 2015. For vector control/insecticide application technologies, lab and field testing of			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 830A / *Deployed Warfighter Protection (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018

insecticide sprayer products identified as promising tools in FY 2015 was conducted with a focus on remotely operated and/or autonomous spraying capabilities. Best performing products/sprayers and technologies tested in FY 2015 transitioned to industry partners for commercialization and submission to the AFPMB for addition to the National Stock System.

FY 2017 Plans:

In FY 2017, the DWFP research program is leading translational research to develop and field tools that protect against emerging infectious disease threats and enable deployed forces to better protect themselves from biting insects, primarily mosquitoes, which transmit force degrading diseases. This is accomplished through research, testing and evaluation of products, patent submissions, licensing, and EPA registrations for new insecticides and bite protection tools. The DWFP continues to maintain its focus on three priority areas: personal protection systems, new insecticides, and vector control/insecticide application technologies. For enhanced personal protection systems, protective clothing technology (bite proof fabric) is patented and transitioning to the U.S. Army Natick Soldier Research, Development and Engineering Center for advanced development; pending results of efficacy testing and EPA registration of the alternative to permethrin for treating combat uniforms, technology is transitioning to the Services for incorporation into future combat uniforms. Within this same focus area under area/spatial repellents, FY 2016 results and EPA registration of transfluthrin is driving commercialization strategies and licensing agreements to field a novel area/spatial-repellent device to provide passive protection from biting mosquitoes. In the insecticides development portfolio, the exploration of natural/biopesticides with improved environmental and human safety profiles continue. Molecular pesticide development and testing partnerships with two major global insecticide developers continues. Field evaluation of first generation, species-specific molecular insecticides targeting mosquitoes is starting; following completion of the AFPMB led Vector Control Capabilities Gap Analysis, the AFPMB pesticides committee has identifed priority insecticide gaps, which drive FY 2017 funding for pesticides-related R&D. For vector control/insecticide application technologies, a new silent backpack sprayer developed by the DWFP program, licensed by industry in FY 2015 and improved by the commercial partner in FY 2016 is becoming commercially available. The program is exploring new technologies to enable remotely operated and/or autonomous insecticide application. Partners are adding data to two vector control mobile apps which serve as decision support tools for deployed entomologists. Technologies developed provide solutions to prevent malaria needed by the President's Malaria Initiative and partners in the WHO Global Malaria Program.

FY 2018 Plans:

In FY 2018, the DWFP research program will continue to lead translational research to develop and field tools that protect against emerging infectious disease threats and enhance protection of deployed forces from biting insects, primarily mosquitoes, which transmit force degrading disease pathogens. The program will also enhance coordination with MIDRP and GEIS programs to strengthen complementary research and surveillance outputs. The completion of the AFPMB Vector Control Capabilities Gap Analysis in FY 2016 will be used to continue acquisition-based research and development requirements in a Capability Needs

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 830A / *Deployed Warfighter Protection (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Assessment. The AFPMB will also develop test and evaluation plans necessary to determine a product's ability to meet these requirements.			
Accomplishments/Planned Programs Subtotals	4.908	4.889	5.123

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Develop, mature and field new or improved products and strategies that protect U.S. forces from disease-carrying insects. Identify acquisition-based research and development requirements in a Capability Needs Assessment. Refine target product profiles and performance criteria. Secure registered trademarks, patents, commercial partners, and/or EPA registration of new or improved insecticides, application technologies and repellent systems. Continue to partner with industry to field products and coordinate with the Services, AFPMB, USAMMDA, DLA and relevant Program Executive Offices to transition efforts.

E. Performance Metrics

Performance for the DWFP program is measured by the insecticides and other products given EPA registration and added to the military stock system, changes in pest management techniques or technologies used by the military to control biting/disease causing insects, patents, and peer-reviewed scientific manuscripts. The Program conducts an annual Research Review during which a panel of DoD subject matter experts provides input on programmatic alignment and strategic priorities.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 478 / *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
478: *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*	0.000	0.000	0.000	14.766	-	14.766	14.754	18.556	18.639	18.724	Continuing	Continuing

A. Mission Description and Budget Item Justification

DoD Cancer Moonshot - Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)

DoD's Cancer Moonshot requirement is a mission of the Murtha Cancer Center (MCC) at USU under the authority of a tri-federal Memorandum of Agreement signed July 2016 by the Acting Assistant Secretary of Defense for Health Affairs (DoD), the Under Secretary of Health, Department of Veterans Affairs(VHA), and the Acting Director of the National Cancer Institute (NIH), for a tri-federal program of Clinical Proteogenomics Cancer Research. DoD's Cancer Moonshot promotes readiness and mission accomplishment of the active duty service member (ADSM) force, as well as military beneficiaries, retirees, and veterans. There are about 1,000 ASDMs who are stricken with a new cancer diagnosis annually, and MCC serves as the DoD's Health Affairs-approved Center of Excellence for cancer care and research for these ADSMs. MCC's mission is to bring translational cancer research to all patients in order to improve their health and mission performance, and to help prevent, screen, detect, and treat cancer; minimize side effects of cancer treatments;, and return to duty ADSMs stricken with cancer, as well all other DoD beneficiaries. DoD's Cancer Moonshot initiative allows for the provision of state-of-the-art molecular analysis of tumors and blood of cancer patients which will result in increased force readiness through more targeted treatment of cancers with fewer side effects, as well as better screening for cancer risk and development.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: DoD Cancer Moonshot - Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)	-	0.000	14.766
Description: Description: DoD's Cancer Moonshot at USU's MCC is a research program consisting of two overall projects, the first known as APOLLO (Applied Organizational Learning and Outcomes), and the second as DoD Framingham. APOLLO is a novel high-throughput molecular analysis of every DNA (gene), RNA, and protein expression molecule in cancer patient tumors. Such analysis has never been done on a large scale across multiple cancer types, and small pilot studies demonstrate that the APOLLO project will result in unprecedented findings across all types of cancer (with specific focus on cancers of the greatest threat to ASDMs). These new findings will be identified by using state-of-the-art tissue collection procedures in the operating rooms of all patients undergoing cancer surgery at MCC collection protocol sites (e.g.. Walter Reed NMMC;NMC Portsmouth; NMC San Diego; Womack AMC; Keesler AFB) and, then, sequencing the entire DNA genome and RNA sequence at USU, while analyzing the entire protein expression profile of these same cancers in MCC's Proteomics Laboratory, as well as other affiliated protein laboratories. The vast molecular data that will be derived from these analyses (in the terabyte			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 478 / *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
and petabyte range and beyond) will be linked to clinical patient data as well as treatment outcomes data. These combined data sets will be housed in National Cancer Institute (NCI) secure cloud-based servers with restricted access for analytics by teams of bioinformatics experts (i.e., from government, university, and corporate entities) across the United States working on this endeavor. This complete bio molecular (global) expression profiling of thousands of cancers of all types seen in military treatment and other facilities will predictably result in a myriad of new discoveries regarding the way cancers develop, progress, respond to treatment, evade treatment, and spread. It also will result in new ways to combat cancers and minimize side effects of cancer treatment, as well as identify novel cancer screening and prevention opportunities, while focusing on militarily-relevant cancers and ADSMs with cancer, distinguishing it from any effort that might develop in the future in a civilian organization, as none of this scale exists today. There are five specific APOLLO sub-projects, which are classified based on the organ type of cancer under study: APOLLO 1 = Lung cancer; APOLLO 2 = Gynecological cancer; APOLLO 3 = Prostate cancer; APOLLO 4 = Breast cancer; and APOLLO 5 = all other cancer types. Both of these projects in the DoD Cancer Moonshot program were specifically developed to focus on ADSM with cancer (readiness), utilize molecular laboratories that are American owned and operated (U.S. DoD and DOE), keep all sensitive de-identified clinical and molecular data on U.S. government computers and servers for maximum data security and analysis (through the NCI), and benefit the nation through any and all discoveries that are made. ***FY 2017 Plans:*** Plans: APOLLO - Collect 800 cancer specimens (lung, gynecologic, prostate, and breast) and run them though the DNA, RNA, and protein molecular analysis lab platforms of USU and perform initial data analytics on the results. ***FY 2018 Plans:*** APOLLO - Collect 1,000 cancer specimens (all cancer types) and run them though the DNA, RNA, and protein molecular analysis lab platforms of USU, and perform initial data analytics on the results. Perform final data analytics on previously analyzed APOLLO samples.			
Accomplishments/Planned Programs Subtotals	-	0.000	14.766

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 478 / *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*

E. Performance Metrics

To be determined.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 479 / *Framingham Longitudinal Study (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
479: *Framingham Longitudinal Study (USUHS)*	-	0.000	0.000	4.920	-	4.920	4.920	4.920	4.920	4.920	Continuing	Continuing

A. Mission Description and Budget Item Justification

DoD Cancer Moonshot Program - DoD Framingham

DoD's Cancer Moonshot requirement is a mission of the Murtha Cancer Center (MCC) at USU under the authority of a tri-federal Memorandum of Agreement signed July 2016 by the Acting Assistant Secretary of Defense for Health Affairs (DoD), the Under Secretary of Health, Department of Veterans Affairs(VHA), and the Acting Director of the National Cancer Institute (NIH), for a tri-federal program of Clinical Proteogenomics Cancer Research. DoD's Cancer Moonshot promotes readiness and mission accomplishment of the active duty service member (ADSM) force, as well as military beneficiaries, retirees, and veterans. There are about 1,000 ASDMs who are stricken with a new cancer diagnosis annually, and MCC serves as the DoD's Health Affairs-approved Center of Excellence for cancer care and research for these ADSMs. MCC's mission is to bring translational cancer research to all patients in order to improve their health and mission performance, and to help prevent, screen, detect, and treat cancer; minimize side effects of cancer treatments;, and return to duty ADSMs stricken with cancer, as well all other DoD beneficiaries. DoD's Cancer Moonshot initiative allows for the provision of state-of-the-art molecular analysis of tumors and blood of cancer patients which will result in increased force readiness through more targeted treatment of cancers with fewer side effects, as well as better screening for cancer risk and development.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: DoD Cancer Moonshot Program - DoD Framingham Longitudinal Study	-	0.000	4.920
Description: DoD Framingham is a novel project that is enabled by the blood serum specimens stored at the DoD Serum Repository at the Armed Forces Health Surveillance Branch (AFHSB) in Silver Spring, Maryland. This facility stores blood serum drawn from over 10 million ADSMs who were required to undergo mandatory semiannual blood testing for the last 25 years, resulting in this repository with over 65 million blood serum specimens. MCC tumor registry data, which includes every ADSM who developed cancer while on active duty, is matched to data in the Serum Repository. This allows MCC to identify the blood serum of ADSMs who ultimately develop cancer at key times, i.e., before they had cancer, during their cancer treatment, and after their successful cancer treatment. Four different serum specimens (two before, one during, and one after cancer diagnosis and treatment) from every ADSM who developed certain types of cancer over a ten-year period of time are then sent to the Nation's foremost protein identification (mass spectroscopy) center, i.e., the Pacific Northwest National Laboratory (PNNL) run by the Department of Energy (DOE). This enables identification of the entire proteome circulating in the blood serum of these cancer patients before, during, and after cancer diagnosis. Comparing the proteomes will allow for identification of new protein biomarkers and indicators of treatment response and failure both of individual patients and across all patients with a specific type of cancer. Smaller studies of this nature done by MCC researchers have proven that this is an effective strategy to identify novel diagnostic and treatment protein expression biomarkers that can be assayed in new blood tests for cancer. This			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 479 / *Framingham Longitudinal Study (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
project will do it “at scale”, i.e. in large numbers of active duty cancer patients (who are otherwise healthy and therefore do not have the “confounding” protein markers of old age, diabetes, and other medical issues). By using serums that go back many years before the ADSM was diagnosed with cancer, the earliest markers of cancer that will be identified, and assays will be performed by another U.S. governmental agency with the best protein detection and analysis tools in the world. Eight specific DoD Framingham sub-projects, classified based on the organ type of cancer, will be conducted: Framingham 1 = Oropharyngeal cancer; Framingham 2 = Lymphoma; Framingham 3 = Bladder cancer; Framingham 4 = Kidney cancer; and Framinghams 5 through 8 subtypes will be determined by MCC and NCI experts in the coming months. Both the APOLLO and Framingham projects in the DoD Cancer Moonshot program were specifically developed to focus on ADSM with cancer (readiness), utilize molecular laboratories that are American owned and operated (U.S. DoD and DOE), keep all sensitive de-identified clinical and molecular data on U.S. government computers and servers for maximum data security and analysis (through the NCI), and benefit the nation through any and all discoveries that are made. ***FY 2017 Plans:*** Identify Framingham 1 (Oropharyngeal) serum specimens and run them through the serum protein analysis lab platform, and perform initial data analytics on the results. A de-identified dataset will be obtained from the Armed Forces Health Surveillance Branch related to serum samples identified by and pulled from the Department of Defense Serum Repository (DoDSR). This data set will include the following: 1) case status (i.e., case or control); 2) year of diagnosis; 3) year of the sample acquisition; 4) year of birth of the subject; 5) gender of the subject; 6) tumor stage at time of diagnosis for the cases; and 7) p16 status at time of diagnosis for the cases. If information on recurrences of the cancer for the case subjects is available, that will be provided as well (i.e., in yes/no format and with date of recurrence if applicable). Specimens to be used in this study will be serum samples from the DoDSR. The DoDSR is a repository of serially collected serum samples obtained from active duty service members from the time of their military in-processing through their discharge, taken at a minimum at two year intervals ***FY 2018 Plans:*** Identify Framingham 2 (Lymphoma) serum specimens and run them through the serum protein analysis lab platform, and perform initial data analytics on the results. A de-identified dataset will be obtained from the Armed Forces Health Surveillance Branch related to serum samples identified by and pulled from the Department of Defense Serum Repository (DoDSR). This data set will include the following: 1) case status (i.e., case or control); 2) year of diagnosis; 3) year of the sample acquisition; 4) year of birth of the subject; 5) gender of the subject; 6) tumor stage at time of diagnosis for the cases; and 7) p16 status at time of diagnosis for the cases. If information on			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 479 / *Framingham Longitudinal Study (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
recurrences of the cancer for the case subjects is available, that will be provided as well (i.e., in yes/no format and with date of recurrence if applicable). Specimens to be used in this study will be serum samples from the DoDSR. The DoDSR is a repository of serially collected serum samples obtained from active duty service members from the time of their military in-processing through their discharge, taken at a minimum at two year intervals			
Accomplishments/Planned Programs Subtotals	-	0.000	4.920

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance Metrics to be determined.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 499 / *MHS Financial System Acquisition*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
499: *MHS Financial System Acquisition*	-	0.000	0.000	13.456	-	13.456	21.129	5.373	1.971	2.011	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Defense Health Program (DHP) appropriations' distribution and execution of funding is currently dispersed amongst multiple, disparate accounting systems, which is in direct conflict with Financial Improvement Audit Readiness (FIAR) guidance prioritizing the standardization of financial management systems and business processes. Currently DHP funding is distributed and executed across three disparate systems.

The current Defense Health Agency (DHA) structure hinders the overarching goal for audit ready initiatives and agency standard financial business processes. The identified solution for DHA to meet these challenges is to deploy a single operational financial management system (FMS) with minimal mission and business impact. DHA is researching a system that will accommodate standard and medically-required business processes. The goal is to transition financial operations to a platform that allows for consistency across the DHA, enabling standardized processes, data collection, and reporting.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: MHS Financial System Acquisition	-	0.000	13.456
Description: The goal is to transition financial operations to a platform that allows for consistency across the Defense Health Agency, enabling standardized processes, data collection, and reporting. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Plans:*** Research to consolidate all DHP appropriations into a single Financial Management System (FMS) system to provide the following capabilities: 1. Improved FMS functionality 2. Financial compliance and accountability 3. Improved business processes and enterprise data visibility 4. Improved cost management structure and financial reporting for the military medical system.			
Accomplishments/Planned Programs Subtotals	-	0.000	13.456

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 499 / *MHS Financial System Acquisition*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA 3: *PE 0807721 Replacement & Modernization*	-	0.000	9.031	0.000	9.031	10.409	22.611	0.000	0.000	Continuing	Continuing

Remarks

D. Acquisition Strategy

Acquisition Strategy is to be determined.

E. Performance Metrics

Performance metrics to be determined.

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Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0604110DHA *I Medical Products Support and Advanced Concept Development*

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
Total Program Element	795.298	172.104	96.602	99.039	-	99.039	117.529	128.055	132.331	142.252	Continuing	Continuing
374A: *GDF-Medical Products Support and Advanced Concept Development*	610.673	96.029	92.602	95.039	-	95.039	113.529	124.055	128.251	138.090	Continuing	Continuing
400Z: *CSI - Congressional Special Interests*	177.716	72.075	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
434A: *Medical Products Support and Advanced Concept Development (AF)*	6.909	4.000	4.000	4.000	-	4.000	4.000	4.000	4.080	4.162	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Products Support and Advanced Concept Development: This program element (PE) provides funding to support: 1-advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA), 2-clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user, 3-prototyping, 4-risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Office for possible integration into the Military Health System (MHS), and 5-medical simulation and training system technologies. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of Department of Defense and multiagency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the MHS. The program also supports the Interagency Strategic Plan for Research and Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, and clinical and rehabilitative medicine. As the research efforts mature, the most promising will transition to medical products and support systems development funding, PE 0605145.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0604110DHA *I Medical Products Support and Advanced Concept Development*

The Army Medical Command received FY 2016 DHP Congressional Special Interest (CSI) research funding focused on Peer-Reviewed Traumatic Brain Injury/ Psychological Health, Joint Warfighter Medical Research, and Core Research funding. Because of the CSI annual structure, out-year funding is not programmed.

For the Air Force Medical Service, funding in this program element supports technology development for the rapid transition of medical products and capabilities from Air Force laboratories, and the ability to perform modifications/enhancements required to integrate commercial off-the-shelf (COTS) and near-COTS products into the military operating environment. Ability to enhance or modify existing COTS is a cost effective technique we should maximize where possible, ensuring warfighters have appropriate technology at hand to care for wounded at the point of injury through definitive care and on to rehabilitation and reintegration at the most efficient cost and schedule possible. Significant benefits can be obtained from rapid insertion of high value/impact technologies into healthcare operations to address capabilities that enter the acquisition life-cycle at high TRL levels that can readily be implemented with significant upside potential. The viability of S&T and translational research with a materiel component cannot be ensured without correctly programmed funding for logical progression and transition of those activities in the product development lifecycle. This PE ensures viability of S&T and translational research efforts with a materiel component by providing programmed funding for logical progression and transition of those activities in the product development lifecycle.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	103.443	96.602	107.382	-	107.382
Current President's Budget	172.104	96.602	99.039	-	99.039
Total Adjustments	68.661	0.000	-8.343	-	-8.343
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	72.075	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-3.414	-			
• Cancer Moonshot	-	-	-8.343	-	-8.343

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 400Z: *CSI - Congressional Special Interests*		
Congressional Add: *427A - Traumatic Brain Injury / Psychological Health*	21.375	0.000
Congressional Add: *441A - Joint Warfighter Medical Research Program*	20.000	0.000
Congressional Add: *455A - Therapeutic Service Dog Training Program (USUHS)*	0.000	0.000
Congressional Add: *464A – Program Increase: Restore Core Research Funding Reduction (GDF)*	30.700	0.000
Congressional Add Subtotals for Project: 400Z	72.075	0.000
Congressional Add Totals for all Projects	72.075	0.000

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0604110DHA *I Medical Products Support and Advanced Concept Development*

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0604110-Medical Products Support and Advanced Concept Development (-$72.075 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$72.075 million).

FY 2016: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+ $72.075 million).

FY 2017: Realignment from DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-$13.403 million) to DHP RDTE PE 0603115-Medical Technology Development for the rebalancing of the Joint Program Committees (+$13.403 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0604110-Medical Products Support and Advanced Concept Development (-$9.738 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+$9.738 million).

FY 2017: Realignment from DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-$7.000 million) as a result of DoD CIO Health Information Technology Optimization review.

FY 2017: Realignment from DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-$2.394 million) to DHP RDTE PE 0603115-Medical Technology Development for Breast, Gynecological and Prostate Cancer Centers of Excellence (+2.394 million).

FY 2018: Realignment from GDF DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-$8.343 million) to DHP RDTE PE 0603115-Medical Technology Development, Uniformed Services University, Applied Proteogenomics Organization Learning and Outcomes (APOLLO) Consortium (+$8.343 million) so support the White House-directed Cancer Moonshot initiative.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 374A / *GDF-Medical Products Support and Advanced Concept Development*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
374A: *GDF-Medical Products Support and Advanced Concept Development*	610.673	96.029	92.602	95.039	-	95.039	113.529	124.055	128.251	138.090	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force -Medical Products Support and Advanced Concept Development: This funding supports 1- clinical trials of promising technologies that may provide solutions for the most pressing medical needs of the Warfighter, 2- accelerated transition of promising technologies to the field, and 3- promulgation of new, evidence-based approaches to the practice of medicine as clinical practice guidelines. Medical products advanced concept development is managed by the Joint Program Committees (JPCs) in the following areas: 1- The Medical Simulation and Information Sciences JPC seeks to promote long-term efficiencies by defining processes improving the electronic healthcare record/other medical related systems, and the implementation of new trends and advancements in technology to improve healthcare access, availability, continuity, cost effectiveness, quality, and patient safety through improved decision making via training, education, and informatics. 2- The Military Infectious Diseases JPC supports the advanced development of systems to rapidly detect pathogens (infectious agents), as well as efforts related to the prevention and management of wound infections and the development of antimicrobial countermeasures and infectious disease-related diagnostic systems. 3- The Military Operational Medicine JPC supports clinical assessments related to interventions for post-traumatic stress disorder, nutrition and dietary supplementation to promote health and resilience, real-time physiological status monitoring, interventions for hearing loss and tinnitus, enhancement of military family and community health and resilience techniques, validation trials for suicide prevention, and the accomplishment of related field studies with end users. 4- Combat Casualty Care JPC supports clinical trials such as those assessing biomarkers (biological indicators) for Traumatic Brain Injury (TBI), and advanced product development related to hemorrhage, extremity trauma, pre-hospital combat casualty care, and en route care. 5- Clinical and Rehabilitative Medicine JPC supports clinical research related to pain management and regenerative medicine.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: GDF – Medical Product Support and Advanced Concept Development	96.029	92.602	95.039
Description: Product support and advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); the accelerated transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user through clinical and field validation studies, prototyping, risk reduction, and product transition efforts for medical information technology applications, and medical training systems technologies.			
FY 2016 Accomplishments: Medical simulation and information sciences conducted engineering and manufacturing development in two primary research tasks -- medical simulation and health information technology and informatics (HITI). Under the medical simulation task: Initiated further development of the Advanced Modular Manikin Core effort, focusing on the development of standardized connectors so that curricula specific peripherals could be attached. Medical Simulation also started development of a proof-of-concept			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 374A / *GDF-Medical Products Support and Advanced Concept Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
task performance assessment tool that incorporates personality and emotional state as determinant components to predict healthcare provider performance during combat casualty care scenarios. Under the HITI task: Began to develop the Digital Biobank prototype which informed the technical, storage, and data policy requirements for DHA Precision Medical and Genomic data integration with MHS Genesis system. Shifted HITI Research focus away from garrison Infrastructure and data management and toward addressing theater/operational medicine information technology research gaps such as capturing and transmitting point of injury data, hands-free data entry for warfighters, aiding DoD stakeholders and in particular military medically related program offices in further defining requirements for the Joint Operational Medical Information System (JOMIS). Revised HITI research roadmap to refine and focus the program of research to information technologies and informatics to support theater and operational medicine. Conducted research product transition efforts ensuring seamless transition of research products to DoD/ VA/Commercial organizations. Worked closely with Department of Veterans Affairs Chief of Informatics for a healthcare data interoperability proof of concept study on Linked Data using JSON (the underlying capability in Bing, Google, Amazon and other prominent web offerings) allowing visibility of data to VA and DoD stakeholders. Military infectious diseases continued optimization of a malaria, dengue, chikungunya, and leptospirosis nucleic acid-based assay panel for the Next Generation Diagnostic System. Continued to support a skin and soft tissue infection clinical study in military trainees at Fort Benning, Georgia. This study is aligned with the National Strategy for Combating Antibiotic Resistance. Military operational medicine continued the evaluation and validation of lower extremity injury risk prediction models targeted towards quantifying fitness for duty in military training and operational populations, biofeedback sensors for use as tools to validate injury models, and mobile technology designed to reduce lower back pain in the military. Collaborated with Defense Center of Excellence to develop clinical practice guidelines for: improved psychotherapies (psychological treatment of mental disorders) for post-traumatic stress disorder (PTSD), the use of pharmaceuticals for the treatment of deployment-related symptoms of PTSD (e.g., improving sleep and reducing nightmares), and interventions related to alcohol and substance abuse and suicide prevention. Completed a study evaluating the efficacy of an intervention designed to support families and Service members throughout the deployment lifecycle. Continued the advanced development of an objective, blood-based PTSD biomarker assay. Continued the advanced development of pharmaceutical (drug) interventions for hearing loss and tinnitus. Continued the validation of clinical protocols that assess the use of nutritional strategies and dietary supplements. Developed gender-specific and gender-neutral standards that apply across garrison and combat operations that are focused on reducing injuries in the total force. Supported the refinement of algorithms to predict core body temperature and estimate physiological work strain from real-time non-invasive measurements (e.g., skin temperature and heart rate) that will be integrated into a physiological health status monitoring system.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 374A / *GDF-Medical Products Support and Advanced Concept Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Combat casualty care hemorrhage and resuscitation research: Completed an initial FDA safety study in humans in support of a FDA Biologic License Application for a spray-dried plasma product; initiated preparation for a larger safety and effectiveness study. Continued clinical studies on the prehospital use of plasma for treatment of patients with traumatic hemorrhage. Continued clinical studies on the use of tranexamic acid, a drug to help control severe bleeding. Continued clinical trials and analyzed research data on a device for killing infectious organisms in fresh whole blood; device will reduce the risk of transmission of pathogens (viruses, bacteria, parasites) and Graft Versus Host Disease (GVHD) in whole blood collected and transfused on the battlefield. Transitioned valproic acid, a drug with the potential to prolong patient survival following severe hemorrhage, from the Navy science and technology program into advanced development; continued initial safety studies in normal volunteers and began effectiveness studies in patients. Transitioned Ethinyl Estradiol 3 Sulfate, a drug for low-volume resuscitation of patients with hemorrhagic shock following severe bleeding after trauma, from the Defense Advanced Research Projects Agency (DARPA) into a joint development program and began preparation for clinical trials. Started clinical studies on extending the shelf life of platelets used for transfusion in theatre. Combat casualty care neurotrauma research Identified advanced technologies/devices that will enable first responders to more precisely triage, assess and monitor severe Traumatic Brain Injury (TBI) casualties in a far forward environment. Continued advanced development of novel biomarker-based TBI diagnostics and point of care diagnostic devices. Completed clinical validation of a smooth pursuit eye tracking device for the treatment of mild TBI associated nystagmus (cross eye) and received FDA clearance. In subjects with moderate to severe TBI, demonstrated no difference in patient and control groups in safety and effectiveness studies of NNZ-2566. In subjects with mild TBI, halted recruitment for safety, effectiveness, and dose trials of NNZ-2566 due to lack of effectiveness. Combat casualty care forward surgical and critical care and en route care research: Continued development of a system providing advanced en route intensive care capabilities. Continued development of data collection systems for battlefield point of injury, mainly in the field of decision assist tools using a physiological opened loop system. Combat casualty care treatments for tissue injury research: Continued to evaluate and promote the development of technologies with the potential to be transitioned from the Peer Reviewed Orthopedic Research Program. Clinical and rehabilitative medicine initiated clinical trials examining the use of evidence-based FDA-approved drugs to eliminate heterotopic ossification, a process by which bone tissue forms outside the skeleton. Expanded FDA-regulated clinical trial enrollment for Sufentanil Nanotab, a battlefield pain management product; submitted a New Drug Application to the FDA. Tri-Service Translational Research continued FY 2014 and started FY 2015 research studies at Military Treatment Facilities recommended for funding to include the recruitment, screening, and enrollment of patients. These efforts focused on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, clinical and rehabilitative			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 374A / *GDF-Medical Products Support and Advanced Concept Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018

medicine, and health services research. For FY 2016, applications focused on precision medicine are being solicited from intramural organizations.

FY 2017 Plans:

Medical simulation and information sciences conducts engineering and manufacturing development in two primary research tasks: medical simulation and health information technology (HITI). Under the medical simulation task: Initiating studies designed to optimize individual learning/optimal timing of an individual's insertion into military medical teams to improve the quality of care and patient safety. Beginning research to develop the underlying architecture to support the development of the future Joint Evacuation and Transport Simulation (JETS) System of Systems. The Gesture Interface effort is further developing candidate interface controls for enhancements to provide for more natural and intuitive medical simulation user interface plus conduct preliminary testing and evaluation of prototyped interface controls. Continues work on the physiology engine to refine algorithms in the current beta version and to increase the content to comply with government needs. Initiating work on defining and validating learning strategies that foster inter-professional team-based learning during the early stages of medical skills training. Medical Simulation and Information Science is updating several serious medical games and transitioning them to the advanced developer. Under the HITI task: conducting research in four topic areas that support Theater and Operational Medicine to include Medical Command and Control: Leading edge options for tracking logistics items across theater using sensors or other novel approaches being used in industry, Synchronous/asynchronous theater/operational medicine approaches for teleconsultation and telementoring, and hands-free electronic record data entry. In accordance with the FY16 NDAA Section 217 above topics are being researched to reduce risk associated with the modernization of existing Military Health System legacy systems in support of Defense Health System Modernization for MHS Genesis and the Joint Operational Medical Information System (JOMIS) MAIS. Conducting prototyping, testing, and supporting the transition of technology products and services to address operational medicine health information technology capability gaps, such as capturing and transmitting point of injury data in a hands-free manner more usable for warfighters to improve quality of care and patient safety. Continue Linked Data proof of concept study on healthcare data interoperability between the DoD and VA. Continue Digital Biobank research to share, store and utilize genomic data with Department of Defense and Veterans Affairs in support of the Precision Medicine Initiative and theater/operational medicine needs.

Military infectious diseases is continuing optimization studies and preparing for clinical validation studies for a malaria, dengue, chikungunya, and leptospirosis nucleic acid-based assay panel to be used on the Next Generation Diagnostic System. Continuing a skin and soft tissue infection clinical study in military trainees at Fort Benning, GA; applying the results towards the prevention and treatment. Initiating a clinical study focusing on the development of a vaccine against S.aureus (bacteria). These studies support the National Strategy for Combating Antibiotic Resistance.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 374A / *GDF-Medical Products Support and Advanced Concept Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Military operational medicine is continuing the validation of lower extremity injury models using biofeedback sensors. Conducting studies aimed at optimizing suicide prevention interventions. Continuing the advanced development of an objective, blood-based for post-traumatic stress disorder (PTSD) biomarker screening assay development with an industry partner. Preparing for the initiation of a clinical study assessing pharmaceutical (drug) interventions for hearing loss and tinnitus. Completing a study testing the efficacy of omega-3 supplementation to prevent and/or reduce suicide behaviors. Conducting clinical studies to evaluate the association between diet composition and health status. Performing studies to evaluate the efficacy of a dietary intervention to improve Warfighters' omega-3 fatty acid status in a garrison feeding environment. Initiating the evaluation of nutritional and other interventions that may prevent and/or minimize musculoskeletal injury in female Warfighters. Transitioning a predictive model measuring thermal work strain using non-invasive measurements (e.g., skin temperature and heart rate) and energy consumption for military tasks to a physiological status monitoring system. Testing and refining algorithms that provide actionable physiological health status to the Service member and unit leader with the goal of integration into a physiologic status monitor system. Combat casualty care hemorrhage and resuscitation research: Initiating expanded safety, effectiveness, and dose studies in humans in support of a FDA Biologic License Application for a spray-dried plasma product. Completing clinical studies on the pre-hospital use of plasma for traumatic hemorrhage. Completing clinical studies on the use of tranexamic acid, a drug to help control severe bleeding. Initiating clinical studies on the Wound Stasis System, a product to control non-compressible hemorrhage within a body cavity. For valproic acid, a drug with the potential to prolong patient survival following severe hemorrhage, completing initial safety studies in normal volunteers and initiating safety, effectiveness, and dose studies in patients. Initiating safety studies in humans using Ethinyl Estradiol 3 sulfate, a drug for low volume resuscitation of patients with hemorrhagic shock following severe bleeding after trauma. Continuing clinical studies on extending the shelf life of platelets used for transfusion in theatre. Combat casualty care neurotrauma research is initiating studies to further develop devices to enable first responders to more precisely triage, assess and monitor moderate and severe Traumatic Brain Injury (TBI) casualties in a far forward environment. Continuing advanced development of novel blood-based biomarker diagnostics for TBI to be used in the hospital and at the point of care to enable monitoring of progression of injury and efficacy of treatment. Validating clinical recommendations for the management of dizziness in mild-TBI patients that includes a comprehensive review and analysis of TBI management and patient outcomes from OIF/ORF. Investigating the utility of transcranial Doppler for the detection of dysfunction in autoregulation of the middle cerebral artery blood flow velocity in mild TBI. Combat casualty care forward surgical and critical care and en route care research: Continuing development of a system providing advanced en route intensive care capabilities such as automated systems; involves studying the impact on patient care outcomes and the provider skill levels required. Initiating assessment of decision assist tools for application on a physiological closed loop system; specifically, an intravenous anesthesia closed loop device. Combat care treatments for tissue injury research: continuing to evaluate and promote the development of technologies with the potential to be transitioned from the Peer Reviewed Orthopedic Research Program.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 374A / *GDF-Medical Products Support and Advanced Concept Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Clinical and rehabilitative medicine is continuing efforts in the areas of military-relevant pain management. Completing advanced clinical trials for Sufentanil Nanotab, a battlefield pain management product. Implementing inter-agency clinical trials on individualized (precision medicine), integrative pain management for Wounded Warriors. Conducting clinical research into protocols for reduction of immunosuppressive drug regimens following composite tissue transplantation. Conducting clinical trials for skin regeneration and muscle regeneration therapies following burn injuries. Tri-Service Translational Research is continuing FY 2014 and 2015 efforts, and beginning FY 2016 tri-Service translational research studies at Military Treatment Facilities and intramural organizations recommended for funding. Applications are being solicited to focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, and clinical and rehabilitative medicine. ***FY 2018 Plans:*** Medical simulation and information sciences will conduct engineering and manufacturing development in two primary research tasks: medical simulation and health information technology (HITI). Under the medical simulation task: Will complete work on the Advanced Modular Manikin core (torso). Will initiate development of low and mid fidelity peripherals that attach or insert onto the core manikin. Research will continue to develop the underlying architecture to support the development of the future Joint Evacuation and Transport Simulation (JETS) System of Systems. Research will continue on the integration of virtual standardized patients and virtual technology applications to represent a broader range of burn training scenarios with increased physiological responsiveness to not only the user's actions but also further environmental exposure. HITI will conduct proof of concept demonstrations for Theater and Operational Medicine, to include Medical Command and Control, Leading edge options for tracking logistics items across theater using sensors or other novel approaches being used in industry, Synchronous/ asynchronous theater/operational medicine approaches for teleconsultation and telementoring, and hands-free electronic record data entry. These topics are being studied to reduce risk in accordance with FY16 NDAA Section 217. Will demonstrate and define medical device interoperability requirements for use of medical devices and patient data in a closed loop to deliver medical care during prolonged field care scenarios in collaboration with FDA, NIST, NIH and other Federal Agencies and industry partners. Will continue efforts to transition technology products and services to external stakeholders in order to address operational medicine health information technology capability gaps, such as capturing and transmitting point of injury data to improve quality of care and patient safety. Will advance Digital Biobank research to store, protect, analyze and share genomic data with Department of Defense and Veterans Affairs in support of the Precision Medicine Initiative. Military infectious diseases will complete optimization studies and continue clinical validation studies for a malaria, dengue, chikungunya, and leptospirosis nucleic acid-based assay panel to be used on the Next Generation Diagnostic System. Will complete a skin and soft tissue infection clinical study in military trainees at Fort Benning, GA, and will apply results towards the			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 374A / *GDF-Medical Products Support and Advanced Concept Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
prevention and treatment. Will prototype diagnostic devices and assay performance in an operational environment to evaluate the potential field application of the assays/device to detect nucleic acids, proteins and/toxins. Will prospectively collect and evaluate standardized infection data including therapy, microbiology, and clinical outcomes of combat-related injuries across treatment facilities. These studies will support the National Strategy for Combating Antibiotic Resistance. Will support adenovirus vaccine production modernization efforts. Military operational medicine will conduct advanced development on a real-time physiological status monitor system. Will initiate development of monitors detecting oxygen toxicity in combat and training environments. Will advance technologies supporting the Integrated Soldier Sensor System to include sensor(s) quantifying the impact of energy expenditure and physical load on Soldier Service members' performance, improved metabolic monitoring in training environments, and the assessment of cognitive status in operational settings via the monitoring of fatigue and nutritional status. Will initiate a clinical study for pharmaceutical (drug) interventions for noise induced hearing loss. Will optimize and validate brief cognitive behavior therapies for decreasing suicide. Will develop guidance regarding calcium and vitamin D intake to support optimal bone health during training. Combat casualty care hemorrhage and resuscitation research: Will continue the expanded safety, effectiveness, and dose studies in humans in support of a FDA Biologic License Application for a spray-dried plasma product. Will continue clinical studies on the Wound Stasis System, a product to control non-compressible hemorrhage within a body cavity. Will pursue knowledge related to new technologies and techniques for the treatment of non-compressible torso hemorrhage on the battlefield. Will complete the clinical trials/clinical effectiveness study and data analysis on a device for killing infectious organisms in fresh whole blood and will initiate preparation of various pre-market application modules for FDA clearance; device will reduce the risk of transmission of pathogens (viruses, bacteria, parasites) and Graft Versus Host Disease (GVHD) in whole blood collected and transfused on the battlefield. Will continue clinical studies supporting FDA licensure of valproic acid, a drug to prolong survival following severe hemorrhage. Continuing clinical studies on extending the shelf life of platelets used for transfusion in theatre. Combat casualty care neurotrauma research will further develop devices to enable first responders to more precisely triage, measure and monitor physiological parameters relevant to the progression of moderate and severe Traumatic Brain Injuries in the battlefield. The program will also leverage data from Combat Operations to improve management of TBI by correlating injury events and medical records. Combat casualty care forward surgical and critical care and en route care research: Will continue advanced development of technology that electronically captures, records, and transmits combat casualty clinical data during evacuation to higher echelons of care. Will continue advanced development efforts towards increment 1 production of an advanced medical monitoring capability, which emphasizes algorithms for early hemorrhage detection. Will continue studies pursuing a trauma indication for restoring blood flow in cases of damaged blood vessels. Will support knowledge studies related to multi-functional resuscitation fluids, the translation of joint En Route care research, safe patient handoffs, and life support in a pre-hospital setting.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 374A / *GDF-Medical Products Support and Advanced Concept Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Clinical and rehabilitative medicine will continue efforts in the areas of military-relevant pain management to include the validation of non-pharmacologic approaches to managing pain. Will continue regenerative medicine to include validation of strategies to modulate the immune system in order to reduce the need for lifelong immunosuppression following transplantation. Will expand advanced clinical trials for oral transmucosal Ketamine, a fast acting, easily dispensed oral battlefield pain management product to assess its effectiveness in managing pain after surgery. Tri-Service Translational Research will continue FY 2015 and FY 2016 tri-Service translational research studies at Military Treatment Facilities and intramural organizations recommended for funding. Applications will be solicited to focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, clinical and rehabilitative medicine.			
Accomplishments/Planned Programs Subtotals	96.029	92.602	95.039

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Test and evaluate medical device prototypes, medical procedures, and drug and vaccine candidates in government-managed Phase 2 clinical trials to gather data required for military and regulatory requirements prior to production and fielding, to include FDA approval and Environmental Protection Agency registration.

E. Performance Metrics

Research is evaluated through In-Progress Reviews, Defense Health Program-sponsored review and analysis meetings, quarterly and annual status reports, and is subject to Program Office or Program Sponsor Representatives progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. In addition, Integrated Product Teams, if established for a therapy or device, will monitor progress in accordance with the DoD Instruction 5000 series on the Operation of the Defense Acquisition System. The benchmark performance metric for transition of research supported in this PE will be the attainment of a maturity level that is typical of Technology Readiness Level 7.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 400Z / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
400Z: *CSI - Congressional Special Interests*	177.716	72.075	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2016 Defense Health Program Congressional Special Interest (CSI) funding supported peer-reviewed directed research for Traumatic Brain Injury and Psychological Health, and Joint Warfighter Medical Research. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 427A - Traumatic Brain Injury / Psychological Health	21.375	0.000
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for research aimed to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and combat-related traumatic brain injury (TBI) on the function, wellness, and overall quality of life, including interventions across the deployment lifecycle for Service members and Veterans, as well as their family members, caregivers, and communities. Key priorities of the FY 2016 Traumatic Brain Injury and Psychological Health (TBI/PH) Research Program were supporting projects aligned with the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service members, and Military Families; enabling significant research collaborations; and complementing ongoing Department of Defense (DoD) efforts to ensure the health and readiness of our military forces by improving upon and optimizing the standards of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In support, the FY 2016 Military Operational Medicine Research Program continued to fund the Military Suicide Research Consortium toward development of state-of-the-art, evidence-based, effective suicide prevention tools and interventions to the DoD. The FY 2016 Combat Casualty Care Research Program initiated studies to inform clinical practice guidelines for the management of TBI by analyzing the Deployed Warrior Medical Management Center and the DoD Trauma Registry casualty treatment data containing Operation Iraqi Freedom/ Operation Enduring Freedom (OIF/OEF) TBI clinical management to determine the best treatment outcome for TBI casualties. Moreover, a clinical study was initiated to validate Virtual Care, Telehealth, and Mobile technology applications to enable far forward medical care for the management of TBI. ***FY 2017 Plans:*** No funding programmed.		
Congressional Add: 441A - Joint Warfighter Medical Research Program	20.000	0.000

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 400Z / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
FY 2016 Accomplishments: The Joint Warfighter Medical Research Program (JWMRP) provides continuing support for promising research previously funded under Congressional Special Interest programs. The focus is to augment and accelerate high priority DoD and Service medical requirements that are close to achieving their objectives, and yielding a benefit to military medicine. Project funding is divided into technology development and engineering and manufacturing development efforts. The JWMRP directly supports military medical research in military infectious diseases, combat casualty care, military operational medicine, medical simulation and information sciences, and clinical and rehabilitative medicine. Through an iterative process of recommendations, prior year CSI-funded projects were nominated for consideration by the Services, Joint Program Committees, and Execution Management Agency activities. Those projects deemed by the Joint Program Committees and Advanced Development Program Managers to have the highest priority to fill critical research or materiel gaps, and those projects close to developing a product were invited to submit a pre-application. All pre-applications were reviewed and full application request for proposals went out in February 2016. The scientific peer review occurred in late May 2016 and programmatic review in late June 2016. Eleven projects were recommended for funding. Awards will be completed by September 2017. ***FY 2017 Plans:*** No funding programmed.		
Congressional Add: 455A - Therapeutic Service Dog Training Program (USUHS) ***FY 2016 Accomplishments:*** No Funding Programmed. Therapeutic Service Dog Training Program transferred to DHP O&M Account. ***FY 2017 Plans:*** No funding programmed.	0.000	0.000
Congressional Add: 464A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative was directed toward DHP core research initiatives in PE 0604110. Funds supported medical products support and advanced concept development in medical simulation and information sciences, military infectious diseases and combat casualty care, and clinical and rehabilitative medicine (Project 374A). ***FY 2017 Plans:*** No funding programmed.	30.700	0.000
Congressional Adds Subtotals	72.075	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 400Z / *CSI - Congressional Special Interests*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

Prior year CSI funded research will be assessed for developmental maturity and qualification for initial or continued advanced development funding. If advanced development criteria are met, follow-on development will be solicited through a peer-reviewed process.

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 434A / *Medical Products Support and Advanced Concept Development (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
434A: *Medical Products Support and Advanced Concept Development (AF)*	6.909	4.000	4.000	4.000	-	4.000	4.000	4.000	4.080	4.162	Continuing	Continuing

A. Mission Description and Budget Item Justification

Air Force Medical Products Support and Advanced Concept Development & Prototyping efforts are focused on achieving rapid transition of promising, high TRL commercially-available off-the-shelf products through minor modifications and/or enhancements to address the most pressing medical needs of the Warfighter, accelerating transition of those technologies to operators in the field. Development, Modification, and Enhancement projects will emphasize technologies supporting Expeditionary Medicine, Human Performance, En-Route Care, Force Health Protection, and Operational Medicine. Funding provides critical flexibility to make and act on materiel solution investment decisions in an annual cycle. Derive benefits from rapid insertion of high value / impact technologies into healthcare operations with programmed funding to address capabilities that enter the acquisition life-cycle at high TRL levels that can readily be implemented with significant upside potential. Program ensures viability of S&T and translational research efforts with a materiel component by providing programmed funding for logical progression and transition of those activities in the product development lifecycle.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Medical Products Support and Advanced Concept Development (AF)	4.000	4.000	4.000

Description: Rapidly transition key COTS and near-COTS based technology solutions to the warfighter through assessment/ evaluation and minor modification or enhancement of solutions to address threshold operational requirements and associated key performance parameters. Provide core capability to rapidly address capability gaps and requirements with affordable state-of-the art commercial technologies in support of the operational mission. Provide core capability to logically progress initiatives and concepts from S&T and translational/knowledge-focused programs (6.1-6.3) into materiel solutions and conduct the advanced development and transition activities needed to ensure those products are fielded in an effective, affordable, timely and efficient manner.

FY 2016 Accomplishments:

Began development of a next generation multi-channel infusion pump via commercially-available technology approach to provide medics with the ability to rapidly and safely deliver multiple drugs and therapeutics to DoD injured personnel in the field, in the air, and awaiting evacuation to meet customer urgent operational requirements. Will also began transitioning of 59 MDW-developed vascular shunt for restoring blood flow to extremities and 60 MDW project for creating ability to vary blood flow for aortic hemostasis and resuscitation balloon treatment for combat casualty care in the Expeditionary Medicine portfolio. Continued development of the Cardiovascular Sonospectrographic Analyzer (CSA) technology through case-evaluations that improve the sensitivity, specificity, and form factor of the device, enabling it to process sound signatures of turbulent blood through partially

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 434A / *Medical Products Support and Advanced Concept Development (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
occluded arteries to the sensitivity level of a CT angiography. Launched project to develop an inline fluid warmer system for special force's medics that reduced weight and cube of existing fluid warmers by 30% and enable treatment at point of injury. ***FY 2017 Plans:*** Continue development, evaluation, modification, and refinement of the multichannel infusion pump to meet customer urgent operational requirement to provide multiple drugs and therapeutics simultaneously for DoD injured personnel. Will obtain FDA approval and complete transition of the 59 MDW's vascular shunt sets to all DoD surgical teams. Will continue development and refinement of variable-flow aortic hemostasis and resuscitation balloon treatment for combat casualty care in developing a prototype field catheter with packaging and inserts for testing in preparation of FDA approval and pending clinical trials. Initiate project to develop commercially-available system for producing upon-demand Intravenous (IV) solutions in deployed EMEDS using onsite water sources that will eventually include reconstitution of dried human plasma when available commercially. ***FY 2018 Plans:*** Complete transition and begin fielding of the multichannel infusion pump to meet urgent operational mission requirement to replace existing multichannel pumps in the MEFPAK inventory that are discontinued by the manufacturer. Will continue development of Medical Modernization efforts including but not limited to transition of the variable-flow aortic hemostasis and resuscitation balloon treatment device for treating combat casualties to licensed vendor who will refine design, obtaining FDA approval, and field catheter kit with packaging and inserts for DoD use and commercial sales; develop commercially-available system for producing upon-demand Intravenous (IV) solutions in deployed EMEDS and Naval vessels using onsite/onboard water sources that will eventually include reconstitution of dried human plasma when available commercially; assess technology that utilizes elemental oxygen to cause immediate coagulation in wounds at the point of injury.			
Accomplishments/Planned Programs Subtotals	4.000	4.000	4.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Partnership with the USAMRMC, Navy Medical Research Center (NMRC), AFRL, AFLCMC, and the Department of the Interior in inter-agency agreements and use (award of delivery orders and task assignments) to engineering, manufacturing, and prototype development IDIQ vehicles awarded under SBIR phase III provisions or similar. Utilization of Small Business Innovative Research program direct awards for Phase III transition efforts and a Cooperative Agreement structure through Foundations supporting military medical research and development programs. Will utilize the Acquisition process managed by the Air Force Life Cycle Management Center (AFLCMC), Wright-Patterson AFB.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 434A / *Medical Products Support and Advanced Concept Development (AF)*

E. Performance Metrics

Achievement of required TRL for each advanced concept development/product support project and fulfillment of established KPPs for same.

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Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605013DHA *I Information Technology Development*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	283.390	16.024	25.340	25.323	-	25.323	19.487	20.641	21.258	21.683	Continuing	Continuing
239B: *Health Services Data Warehouse (Air Force)*	1.766	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
239F: *IM/IT Test Bed (Air Force)*	7.709	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
239G: *Clinical Enterprise Intelligence Program (CEIP) (DHA)*	0.000	1.877	0.962	1.436	-	1.436	1.461	1.490	1.520	1.550	Continuing	Continuing
239H: *IM/IT Test Bed (Air Force) at DHA*	0.000	0.000	1.837	2.222	-	2.222	2.686	2.740	2.795	2.851	Continuing	Continuing
283C: *Medical Operational Data System (MODS) (Army)*	3.114	2.601	2.678	2.705	-	2.705	2.732	2.759	2.787	2.842	Continuing	Continuing
283D: *Army Medicine CIO Management Operations*	0.120	0.368	0.794	0.000	-	0.000	0.000	0.000	0.000	0.378	Continuing	Continuing
283H: *Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)*	0.000	0.125	0.080	0.080	-	0.080	0.080	0.000	0.000	0.000	Continuing	Continuing
283J: *Antibiotic Resistance Monitoring and Research (ARMoR-D)*	0.738	0.844	0.878	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283L: *Pharmacovigilance Defense Application System*	0.274	0.350	0.400	0.350	-	0.350	0.350	0.350	0.350	0.350	Continuing	Continuing
283M: *Business Intelligence Competency Center (BICC)*	1.488	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283N: *Corporate Dental System (CDS)*	0.709	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283P: *Mobile HealthCare Environment (MHCE)*	0.000	0.362	0.300	0.417	-	0.417	0.331	0.473	0.364	0.000	Continuing	Continuing
385A: *Integrated Electronic Health Record Inc 1 (Tri-Service)*	146.417	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency										Date: May 2017		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605013DHA *I Information Technology Development*							
386A: *Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)*	14.464	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
423A: *Defense Center of Excellence (FHP&RP)*	3.464	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
423B: *Defense Center of Excellence (Army)*	0.996	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
423C: *Defense Center of Excellence (T2T/PBH TERM) (DHA)*	0.000	0.000	1.369	1.395	-	1.395	1.422	1.450	1.478	1.509	Continuing	Continuing
435A: *NICOE Continuity Management Tool*	2.855	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
446A: *Disability Mediation Service (DMS)*	0.887	0.399	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480B: *Defense Medical Human Resources System (Internet) (DMHRSi) (Tri-Service)*	0.585	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480C: *Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)*	13.710	1.780	2.326	2.363	-	2.363	0.000	0.000	0.000	0.000	Continuing	Continuing
480D: *Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)*	8.052	0.000	6.140	6.025	-	6.025	5.559	6.416	6.902	7.040	Continuing	Continuing
480F: *Executive Information/ Decision Support (EI/DS) (Tri-Service)*	5.936	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480G: *Health Artifact and Image Management Solution (HAIMS) (Tri-Service)*	8.123	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480K: *Integrated Federal Health Registry Framework (Tri-Service)*	3.652	0.413	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency										Date: May 2017		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605013DHA *I Information Technology Development*							
480M: *Theather Medical Information Program - Joint (TMIP-J) (Tri-Service)*	28.731	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480P: *Other Related Technical Activities (Tri-Service)*	4.139	0.000	1.683	3.500	-	3.500	0.000	0.000	0.000	0.000	Continuing	Continuing
480Y: *Clinical Case Management (Tri-Service)*	2.925	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
481A: *Theather Enterprise Wide Logistics System (TEWLS) Tri-Service)*	5.127	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
482A: *E-Commerce (DHA)*	7.803	2.665	2.829	3.704	-	3.704	4.200	4.284	4.370	4.457	Continuing	Continuing
490I: *Navy Medicine Chief Information Officer*	6.237	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
490J: *Navy Medicine Online*	3.369	1.890	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480A: *Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) (Tri-Service)*	0.000	2.350	1.791	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480Z: *Patient Assessment Screening Tool Outcome Registry (Tri-Service)*	0.000	0.000	0.828	0.538	-	0.538	0.000	0.000	0.000	0.000	Continuing	Continuing
480R: *Joint Disability Evaluation System IT (DHA)*	0.000	0.000	0.445	0.588	-	0.588	0.666	0.679	0.692	0.706	Continuing	Continuing
Program MDAP/MAIS Code: **Project MDAP/MAIS Code(s):** 465												

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key technologies to overcome medical and military unique technology barriers. Programs include Army service level support for the Medical Operational Data System (MODS); Army Medicine CIO Management Operations; Psychological and Behavioral Health – Tools for Evaluation, Risk, and Management (PBH-TERM); Antibiotic Resistance Monitoring and Research (ARMoR-D); Pharmacovigilance Defense Application System (PVDAS); Mobile HealthCare Environment (MHCE); and the Defense Center of Excellence (DCoE).

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605013DHA *I Information Technology Development*

The Navy Medical Command RDT&E funding supports the development required for those systems which are integral to Navy Medicine (i.e., Navy Medicine Online (NMO)). Navy Medicine also funds, when appropriate, a number of small-scale, opportunistic business improvements when the technology makes a sudden advance. These projects are generally not in the scope of the TRICARE Management Activity (TMA) Central Programs such as the development/integration of Defense Optical Fabrication Enterprise Management System (DOFEMS) into a fully automated system to support workload distribution, performance metrics, staffing requirements, supply management, calculation of operating costs from the current independently or manually DOFEMS system. This effort will be a web based centralized management tool and provide a standalone standard set of Lab Management software for all 26 Navy labs. Additionally, the re-design of HIV Management System (HMS) will be more user friendly, less time to perform everyday tasks and prevents the need to maintain separate databases. The re-design will also automate and minimize functions that require manual assistance and assist in fulfilling new requirements.

For the Air Force Medical Service (AFMS), this program element supports IM/IT development requirements within four AFMS Chief Information Officer defined core capabilities as essential to Air Force Medical Service IM/IT mission support. Data warehousing, reporting services, systems integration, and custom application development are featured in almost all IM/IT systems and application requests. The information needs of the AFMS are growing in volume, complexity, and delivery formats. In order to meet future requirements, aggregation of more and varied data sources require increasingly complex data warehousing capabilities. Demand for dynamic analytic capability will require investments in business intelligence, predictive analytic tools, open source research data models, and emerging personalized medicine analysis. Information is still largely produced in an ad hoc manner without standard methodologies, mapping of business requirements, transparent analytic models, and distributed by office productivity software. Centralized production of standard reports, balance sheets, and dynamic query tools would relieve many managers and action officer of routine work and increase leadership decision support. AFMS medical readiness reporting and tracking has set the standard in the DoD for over a decade but multiple applications now encompass what has merged into a common process of tracking unit capability and personal health assessments. Consolidation of medical readiness applications would streamline disability, medical readiness, deployment surveillance, and flying status tracking and reporting who currently must move between multiple applications.

For the Air Force, the funding in this program element provides for sustainment of the IM/IT Test Bed (IMIT-TB) capability, which is a dedicated OT location and staff encompassing the entire spectrum of healthcare services and products available in MTFs, to provide risk controlled testing of designated core and interim medical applications in a live environment.

Defense Health Agency (DHA) Health Information Technology (HIT) [previously known as Tri-Service IM/IT] - DHA HIT RDT&E activities includes funding for development/integration, modernization, test and evaluation for the Defense Health Agency initiatives, and any special interest that are shared within all centralized components of the Defense Health Program (DHP).

The DHP RDT&E appropriation includes the following TMA initiatives: Electronic Commerce System (E-Commerce): This system was developed for centralized collection, integration, and reporting of accurate purchased care contracting and financial data. It provides an integrated set of data reports from multiple data sources to management, as well as tools to control the end-to-end program change management process. E-Commerce is composed of several major applications including: Contract Management (CM), utilizing Prism software to support contract action development and documentation; Resource Management (RM), employing Oracle Federal Financials and TED interface software to support the budgeting, accounting, case recoupment, and disbursement processes; Document Management, utilizing Document software to provide electronic storage, management, and retrieval of contract files; Management Tracking and Reporting, utilizing custom software to provide reports to assist in the management and tracking of changes to the managed care contracts as well as current and out year liabilities; the Purchased Care and

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605013DHA *I Information Technology Development*

Contractor's Resource Center web sites that provide up-to-date financial information for both TMA and the Services concerning the military treatment facilities (MTFs), and expenditures for MTF enrollee purchased care and supplemental care. E-Commerce includes an infrastructure of over 60 servers supporting development, test, and production. E-Commerce is employed by several hundred users in more than 7 different organizations. Project oversight and coordination must be provided to ensure that the needs of the disparate organizations are met without influencing system performance or support to any individual user. Server configurations must remain current with respect to security policies, user authorizations, and interactions with other systems and functions. All of these activities must be managed and coordinated on a daily basis.

Disability Mediation Service (DMS): The VTA (Veteran's Tracking Application) has been the primary system to track, record, and report data for the IDES (Integrated Disability Evaluation System) process. The VTA is scheduled to sun-set, by VA (Veterans Affairs), and the data is being moved to another application. Migration of VTA to another application creates the requirement to allow data exchange between Service non-medical case management and new VA DES (Disability Evaluation System) IT application. The BEC (Benefits Executive Council) is looking to create a DMS (Disability Mediation Service), which is an integrator between the Services and VA.

The DMS will facilitate the improvement of non-medical case management tracking and IDES data/information management. It will eliminate redundant data entry within DoD (Department of Defense), improving data quality by capturing more data for operational reporting from the Services and WCP, decrease backlog by eliminating data entry duplication, and minimize impact to DoD Services by allowing the Services to continue using their existing/planned systems without requiring retraining on a new applications.

The DMS will be created from existing technology. It will provide a mediation service to help isolate each system from changes and uniqueness in the other systems and allow the Services and WCP to report and drill down on data that we capture during the exchange. This IT solution will not replace current DoD systems, but will require some modifications and enhancements to those systems to support the date exchange. WCP will support development costs for these efforts. Services will assume responsibility and POM costs for modifications, enhancements, and maintenance in the out years."

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	19.312	25.340	28.814	-	28.814
Current President's Budget	16.024	25.340	25.323	-	25.323
Total Adjustments	-3.288	0.000	-3.491	-	-3.491
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-1.837	-			
• SBIR/STTR Transfer	-1.451	-			
• PDM D2D - realign funds for an enterprise-wide IT function	-	-	-3.491	-	-3.491

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605013DHA *I Information Technology Development*

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605013-Information Technology Development to Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (-$1.451 million).

FY 2017: No Change

FY 2018: Realignment from DHP RDT&E PE 0605013-Information Technology Development funds (-$3.491 million) and manpower to an enterprise-wide IT function within MHS Procurement.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 239B / *Health Services Data Warehouse (Air Force)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
239B: *Health Services Data Warehouse (Air Force)*	1.766	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Previously known as Assessment Demonstration Center (ADC), Health Services Data Warehouse (HSDW) addresses and focuses on Air Force Medical Service (AFMS) Data Strategy under the DoD and AF Net Centric Enterprise Services. HSDW will develop an Enterprise Data Warehouse (EDW) and Data Marts consolidating databases and transition to a SOA architecture. Program will improve data collection, aggregation, analysis, and data visualization of medical information. New data models will allow rapid development of enterprise-wide reports utilizing Business Intelligence tools.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: 239B - Health Services Data Warehouse	0.000	0.000	-	-	-
Description: AFMS will purchase COTS software/licenses and build custom scripts for development of the data warehouse. The COTS software will expedite consolidation and cleansing of data, measure data quality, merge and organize data for reporting tools. These efforts will be used to complete the transition of CDM data into the HSDW. ***FY 2016 Accomplishments:*** Requirements and funding rolled up under Clinical Enterprise Intelligence Program (CEIP) (DHA) Project Code 239G. Funding transferred to Defense Health Agency Health Information Technology (DHA HIT) from Air Force Medical Information Technology with the stand up of Defense Health Agency beginning in FY 2016. ***FY 2017 Plans:*** Requirements and funding rolled up under Clinical Enterprise Intelligence Program (CEIP) (DHA) Project Code 239G. Funding transferred to Defense Health Agency Health Information Technology (DHA HIT) from Air Force Medical Information Technology with the stand up of Defense Health Agency beginning in FY 2016.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	-	-	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 239B / *Health Services Data Warehouse (Air Force)*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 239F / *IM/IT Test Bed (Air Force)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
239F: *IM/IT Test Bed (Air Force)*	7.709	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Dedicated operational test (OT) location and staff encompassing the entire spectrum of healthcare services and products available in Military Treatment Facilities (MTFs), to provide realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. Critical component of ongoing capability development & fielding efforts, ensuring that each is supported by an independent, unbiased assessment of effectiveness, suitability, security, and survivability in a realistic operational environment as required by the FAR 46.103, DoD 5000, and AFI 99-103. The AFMISTB is a complementary service to existing MHS developmental, integration, interoperability, and security testing facilities, forming a logical test process continuum leading to effective deployment decisions. Outcomes include decreasing life-cycle costs of IM/IT products by catching errors early in the acquisition process where they are less costly to fix, and increasing patient safety by fielding operationally tested medical information systems.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: 239F IM/IT Test Bed (Air Force)	0.000	0.000	-	-	-
Description: Provide realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. Critical component of ongoing capability development & fielding efforts, ensuring that each is supported by an independent, unbiased assessment of effectiveness, suitability, security, and survivability in a realistic operational environment as required by the FAR 46.103, DoD 5000, and AFI 99-103. The AFMISTB is a complementary service to existing MHS developmental, integration, interoperability, and security testing facilities, forming a logical test process continuum leading to effective deployment decisions. Outcomes include decreasing life-cycle costs of IM/IT products by catching errors early in the acquisition process where they are less costly to fix, and increasing patient safety by fielding operationally tested medical information systems.					
FY 2016 Accomplishments: Conduct realistic, risk controlled testing for the new $11B DHMSM Electronic Health Record; also Follow on Test and Evaluation for TMIP, DMIX and HAIMS at Initial Operational Capability sites. Continue ongoing capability development & fielding efforts for half a dozen other ACAT III programs. Assist Joint Operational Medicine Information Systems (JOMIS) to develop and test the new EHR OM program at AF SG5T site in Fort Detrick, MD. Complete DIACAP reaccreditation for AF SG5T VPN. Participate in at least half a dozen AF SG HPTs and requirement reviews.					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 239F / *IM/IT Test Bed (Air Force)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Operational control of funding was transferred from Air Force Medical Information Technology (IT) to Defense Health Agency Health Information Technology (DHA HIT) with the stand up of Defense Health Agency beginning in FY16. Reported under initiative IM/IT Test Bed (Air Force) at DHA Project Code 239H. ***FY 2017 Plans:*** Operational control of funding was transferred from Air Force Medical Information Technology (IT) to Defense Health Agency Health Information Technology (DHA HIT) with the stand up of Defense Health Agency beginning in FY16. Reported under initiative IM/IT Test Bed (Air Force) at DHA Project Code 239H. DHA will transfer funds back to Air Force during year of execution.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	-	-	-

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• N/A: *N/A*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 239G / *Clinical Enterprise Intelligence Program (CEIP) (DHA)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
239G: *Clinical Enterprise Intelligence Program (CEIP) (DHA)*	0.000	1.877	0.962	1.436	-	1.436	1.461	1.490	1.520	1.550	Continuing	Continuing

A. Mission Description and Budget Item Justification

The goal of the Clinical Enterprise Intelligence Program (CEIP) strategic initiative is to advance patient-centered healthcare delivery through integration of informatics and thus transforming our enterprise to a rapid learning organization. The CEIP platform is a combination of hardware, software and technologists that together deliver the ability to use enterprise clinical data. The collection of these capabilities enables CEIP projects. These capabilities are in the following: Program Management, Data Warehousing, Application Portal; Infrastructure and Operations; Application Support; Business Intelligence; Analytics. Types of projects enabled by this platform include clinical dashboards, reports, data feeds, ad-hoc data requests, and data-mart.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: CEIP Platform Integration	1.877	0.962	1.436	-	1.436
Description: The CEIP platform is a combination of hardware, software and technologists that together deliver the ability to use enterprise clinical data. ***FY 2016 Accomplishments:*** The Clinical Enterprise Intelligence Program (CEIP) is a support effort for the DHA to provide both comprehensive project management for the Health Informatics programs and subject matter expertise to sustain the clinical information systems. This program enables DHA to continue their operations to monitor, extract, and make available business medical data from constituent military treatment facilities (MTF). The Clinical Enterprise Intelligence Program (CEIP) is an advanced patient-centered healthcare delivery informatics platform that is transforming our enterprise to a rapid learning organization. The CEIP platform is a combination of hardware, software and technologists that together, deliver the ability to use enterprise clinical data. The collection of these capabilities enables CEIP projects. These capabilities are in the following: Program Management, Data Warehousing, Application Portal, Infrastructure, Operations, Application Support, Business Intelligence, and Analytics. Types of projects enabled by this platform include clinical dashboards, reports, data feeds, ad-hoc data requests, and data-marts from the Health Services Data Warehouse and various other data sources. The CEIP contains the Health Informatics Suite (HIS), Population Health Portal(PHP), Diabetes Information Technology System (DITS) , Health Systems Data Warehouse (HSDW) with multiple data marts, Business Intelligence(BI), Composite Occupational Health and Operation Risk Tracking (COHORT), Referral Management System (RMS), CarePoint Application Portal (CAP)(CHAS III) , CHAS I & II, ORISE Fellowship, Health Systems					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 239G / *Clinical Enterprise Intelligence Program (CEIP) (DHA)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Medical Informatics (HSMI) Infrastructure & Program Office (PO), BDQAS Support, Community of Responsible Choices(CORC), Service Delivery Assessment (SDA), Electronic Data Quality (eDQ), Analytics, and Business Intelligence Competency Center (BICC). CEIP is also in the process of developing and modernizing the Clinical Data Mart (CDM) and SECDEF MHS Review Performance Management Systems (PMS). ***FY 2017 Plans:*** The Clinical Enterprise Intelligence Program (CEIP) is a platform that will enable DHA to continue their operations to monitor, extract, and make available business medical data from constituent military treatment facilities (MTF). With the combination of hardware, software and technologists together, the platform will help use enterprise clinical data. These capabilities are in the following: Program Management, Data Warehousing, Application Portal, Infrastructure, Operations, Application Support, Business Intelligence, and Analytics. Types of projects enabled by this platform include clinical dashboards, reports, data feeds, ad-hoc data requests, and data-marts from the Health Services Data Warehouse and various other data sources. The CEIP contains the Health Informatics Suite (HIS), Population Health Portal(PHP), Diabetes Information Technology System (DITS) , Health Systems Data Warehouse (HSDW) with multiple data marts, Business Intelligence(BI), Composite Occupational Health and Operation Risk Tracking (COHORT), Referral Management System (RMS), CarePoint Application Portal (CAP)(CHAS III) , CHAS I & II, ORISE Fellowship, Health Systems Medical Informatics (HSMI) Infrastructure & Program Office (PO), BDQAS Support, Community of Responsible Choices(CORC), Service Delivery Assessment (SDA), Electronic Data Quality (eDQ), Analytics, and Business Intelligence Competency Center (BICC). ***FY 2018 Base Plans:*** CEIP will continue sustainment and maintenance of CEIP including program management, configuration management, technical refresh, commercial software licenses, data maintenance,Ad Hoc report maintenance, product /help desk support, cybersecurity compliance, software maintenance, test and evaluation activities, and cost of operating site personnel. Additionally, Health Services Data Warehouse (HSDW), one of the applications under CEIP, will continue to be modernized for scalability to maintain high performance while consolidating, integrating and storing clinical and administrative data from across the DoD for over 9.4 million beneficiaries. The goal of the CEIP strategic initiative is to advance patient-centered healthcare delivery through integration of informatics and thus transforming our enterprise to a rapid learning healthcare organization. The CEIP platform is a combination of hardware, software and technologists that together deliver the ability to use enterprise clinical					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 239G / *Clinical Enterprise Intelligence Program (CEIP) (DHA)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
data. Types of projects enabled by this platform include clinical dashboards, reports, data feeds, ad-hoc data requests, data-mart, and work to consolidate the current legacy data into a common data environment.					
Accomplishments/Planned Programs Subtotals	1.877	0.962	1.436	-	1.436

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	26.831	29.435	31.191	-	31.191	28.319	28.699	29.248	29.221	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources. Performance metrics for specific projects may be viewed at the OMB Federal IT Dashboard website.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 239H / *IM/IT Test Bed (Air Force) at DHA*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
239H: *IM/IT Test Bed (Air Force) at DHA*	0.000	0.000	1.837	2.222	-	2.222	2.686	2.740	2.795	2.851	Continuing	Continuing

A. Mission Description and Budget Item Justification

Continue to provide realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. Critical component of ongoing capability development & fielding efforts, ensuring that each is supported by an independent, unbiased assessment of effectiveness, suitability, security, and survivability in a realistic operational environment as required by the FAR 46.103, DoD 5000, and AFI 99-103. The AFMISTB is a complementary service to existing MHS developmental, integration, interoperability, and security testing facilities, forming a logical test process continuum leading to effective deployment decisions. Outcomes include decreasing life-cycle costs of IM/IT products by catching errors early in the acquisition process where they are less costly to fix, and increasing patient safety by fielding operationally tested medical information systems.

Previously reported under initiative IM/IT Test Bed (Air Force) Project Code 239F.
Operational control of funding was transferred from Air Force Medical Information Technology (IT) to Defense Health Agency Health Information Technology (DHA HIT) with the stand up of Defense Health Agency beginning in FY16. However, functionality for operational testing will remain with Air Force Medical IT. Funding will be transferred to Air Force Medical IT during year of execution.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Operational Testing Service	0.000	1.837	2.222	-	2.222
Description: A dedicated operational testing service, Test Bed conduct tests on various Air Force Medical Systems (AFMS). It provides risk controlled testing for designated core & interim medical applications in an operationally realistic environment.					
FY 2016 Accomplishments: DHA transferred funding back to Air Force Medical IT during year of execution. Air Force Medical IT will conduct realistic, risk controlled testing for the new $11B DHMSM Electronic Health Record; also Follow on Test and Evaluation for TMIP, DMIX and HAIMS at Initial Operational Capability sites. Capability development & fielding efforts for half a dozen other ACAT III programs have continued as well as assisting Joint Operational Medicine Information Systems (JOMIS) to develop and test the new EHR OM program at AF SG5T site in Fort Detrick, MD.					
FY 2017 Plans:					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 239H / *IM/IT Test Bed (Air Force) at DHA*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
DHA will transfer the funding back to Air Force Medical IT during year of execution. Air Force Medical IT will continue realistic, risk controlled testing for $13B Central and Air Force programs including: DHMSM Electronic Health Record, JOMIS, Legacy TMIP, DMIX and HAIMS. Multi-Service Operational Test and Evaluation(s) will be conducted for the DHMSM Fixed Facility sites and the JOMIS Operational Medicine locations. Plans are to continue capability development & fielding efforts for half a dozen other ACAT III programs, initiate the Risk Management Framework reaccreditation for AF SG5T VPN for virtualization of IT Test Bed, and participate in at least half a dozen AF SG HPTs and requirement reviews. ***FY 2018 Base Plans:*** As in prior years, DHA will transfer funding to AF Medical IT during year of execution. AF will continue to test the DHMSM Electronic Health Record, JOMIS, Legacy TMIP, DMIX and HAIMS. Multi-Service Operational Test and Evaluation(s) will be conducted for the DHMSM Fixed Facility sites and the JOMIS Operational Medicine locations. Plans are to continue capability development & fielding efforts for half a dozen other ACAT III programs, initiate the Risk Management Framework reaccreditation for AF SG5T VPN for virtualization of IT Test Bed, and participate in at least half a dozen AF SG HPTs and requirement reviews, similar to FY17.					
Accomplishments/Planned Programs Subtotals	0.000	1.837	2.222	-	2.222

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Operational control of funding was transferred from Air Force Medical Information Technology (IT) to Defense Health Agency Health Information Technology (DHA HIT) with the stand up of Defense Health Agency beginning in FY16. However, functionality for operational testing will remain with Air Force Medical IT. Funding will be transferred to Air Force Medical IT during year of execution.

E. Performance Metrics

As determined by and based on the requirements for Air Force Medical IT operational testing.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 283C / *Medical Operational Data System (MODS) (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
283C: *Medical Operational Data System (MODS) (Army)*	3.114	2.601	2.678	2.705	-	2.705	2.732	2.759	2.787	2.842	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding for the Medical Operational Data System (MODS) to deploy modernized data visualization capabilities to enhance Army Unit and Individual Medical Readiness Reporting. MODS provides Army leadership with a responsive and reliable human resource and readiness information management data system for all categories of military and civilian medical and support personnel. MODS provide Tri-Service support through applications such as Electronic Profile, Behavioral Health, and Medical Education.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Medical Operational Data System (MODS)	2.601	2.678	2.705	-	2.705
Description: Information management system to provide responsive and reliable human resource and medical readiness data for all categories of military and civilian medical and support personnel.					
FY 2016 Accomplishments: FY 2016 certification/funding made it possible for the MODS program to complete developmental design of the Electronic Profile System using the Three-Tiered Object-Oriented Architecture. In addition, all design processes and products were verified and validated by a senior Federally-Funded Research and Development (FFRDC) Team – MITRE. The Human Resources suite of applications used this model in parallel. Additionally, the full production increment of Medical Readiness Transformation and ESB Pilot was executed.					
FY 2017 Plans: FY 2017 funds are being used to respond to Milestone Decision Authority decisions to add new capabilities, significantly enhance, and technically upgrade existing capabilities, and use federally funded research and development center resources for system engineering and acquisition effectiveness services. These technology upgrades will support the system's ability to help strengthen the scientific basis for decision-making in patient safety and quality performance within the MHS.					
FY 2018 Base Plans: FY 2018 funds will be used to respond to Milestone Decision Authority decisions to add new capabilities, significantly enhance, and technically upgrade existing capabilities, and use federally funded research and development center resources for system engineering and acquisition effectiveness services. These technology					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283C / *Medical Operational Data System (MODS) (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
upgrades will support the system's ability to help strengthen the scientific basis for decision-making in patient safety and quality performance within the MHS.					
Accomplishments/Planned Programs Subtotals	2.601	2.678	2.705	-	2.705

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	12.596	12.984	13.385	-	13.385	13.628	13.878	13.937	14.076	Continuing	Continuing
• BA-3, 0807721HP: *Replacement/Modernization*	0.120	0.620	0.300	-	0.300	0.400	0.200	0.202	0.204	Continuing	Continuing

Remarks

D. Acquisition Strategy

Select the business, technical, and contract actions that will minimize cost, reduce program risk, and remain within schedule while meeting program objectives.

E. Performance Metrics

1. MEASURE: Data Warehouse reduces total number of database maintenance hours.
METRIC: % database maintenance hours = number of monthly database maintenance hours/total database maintenance hours of previous year average.

2. MEASURE: Data Warehouse supports queries and reports with few data errors (information quality/accuracy).
METRIC: % of reports and queries that contain data errors = total number of reports and queries with data errors /total number of reports and queries.

3. MEASURE: Data Warehouse provides the data needed by users and applications (information quality/completeness).
METRIC: % post-Data Warehouse = total number (post-Data Warehouse) queries and reports/total number (pre + post-Data Warehouse) queries and reports.

4. MEASURE: Three-Tier Object Oriented Architectural Design (3TOOAD) benefits are reduced costs for implementation of new functionalities.
METRIC: % of labor cost = cost of MSR for functional implementation/average cost of similar MSR from previous year(s).

5. MEASURE: Organizational and individual impact of Data Warehouse, 3TOOAD, and Robust Business Intelligence.
METRIC: >= 8.5 avg. benchmark score (0 to 10 scale) on quarterly quality and impact surveys from users.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 283D / *Army Medicine CIO Management Operations*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
283D: *Army Medicine CIO Management Operations*	0.120	0.368	0.794	0.000	-	0.000	0.000	0.000	0.000	0.378	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Army Medicine CIO Management Operations program includes development projects for Army service level support. Specifically, the Army Medicine CIO Management Operations encompasses the Army Medical CIO's Information Management/Information Technology (IM/IT) development activities to ensure compliance with Congressional, Office of Management and Budget, DoD, and Military Health System requirements.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: 283D - Army Medicine CIO Management Operations	0.368	0.794	0.000	-	0.000
Description: The Army Medicine CIO Management Operations will provide system development, engineering, and testing requirements of interim Army medical applications in an operationally realistic, risk controlled test environment to comply with Congressional, Office of Management and Budget, DoD, and Military Health System requirements. ***FY 2016 Accomplishments:*** For FY 2016, the funding was used in developing and enhancing a system that will provide system development, engineering, and testing requirements of Army Medical applications, which provides realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. ***FY 2017 Plans:*** For FY 2017, the funding are being used to develop and enhance a system that provides system development, engineering, and testing requirements of Army Medical applications, which provides realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. These system developments support the Army's ability to help strengthen the scientific basis for decision-making in patient safety and quality performance within the Military Health System. ***FY 2018 Base Plans:*** No funding programmed.					
Accomplishments/Planned Programs Subtotals	0.368	0.794	0.000	-	0.000

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283D / *Army Medicine CIO Management Operations*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	37.730	25.070	25.820	-	25.820	17.110	20.730	22.500	22.950	Continuing	Continuing
• BA-1, 0807721HP: *Replacement/Modernization*	0.060	3.186	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
• BA-1, 0807798HP: *Management Headquarters*	2.463	2.890	2.784	-	2.784	2.830	2.880	2.879	2.882	Continuing	Continuing
• BA-1, 0807796HP: *Base Operations*	0.498	0.510	0.522	-	0.522	0.536	0.536	0.536	0.536	Continuing	Continuing

Remarks

Controls for AMCMO were reduced to support the Desktop to Datacenter initiative that transferred funding to DHA HIT, per the FY18 POM MOA.

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Periodic management evaluation based on ability to provide system development, engineering, and testing requirements of new Army medical applications.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283H / *Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
283H: *Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)*	0.000	0.125	0.080	0.080	-	0.080	0.080	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The US Army Medical Command (MEDCOM) and Defense Centers of Excellence (DCoE) have partnered to develop this information technology project for joint Service level support. The PBH-TERM platform addresses two congressionally mandated initiatives including the behavioral health management within the Warrior Transition Command (GH risk Management module/BHRM and within primary care settings (FIRST-STEPS). Further development efforts allow expansion of capabilities to deliver ongoing user support and training via web-based modules within PBH-TERM and will provide costs casings in terms of staffing requirements, conferencing and reporting.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Psychological and Behavioral Health – Tools for Evaluation, Risk, and Management (PBH-TERM)	0.125	0.080	0.080	-	0.080
Description: PBH-TERM is a web-based psychological and Behavioral Health (BH) information technology platform, which supports evidence-based, standardized and integrated BH risk and case management initiatives as well as program evaluation for the Warrior Transition Command and Patient/Soldier-Centered BH (PCBH) care in primary care settings. ***FY 2016 Accomplishments:*** FY 2016 funds were used to add self-service functionality with direct input by the eligible beneficiaries, which improve health system visibility. RDT&E funding of $125K was used to support a web-based system hosted on the US Army Medical Information Technology Center (USAMITC) server. PBH-TERM is an existing certified web-based platform for primary care behavioral case management tracking and evaluation. ***FY 2017 Plans:*** FY 2017 funds are being used to continue to modify the self-service functionality through adding a “view” only feature, which allows enhanced visibility by authorized BH providers. Adds program management module for marriage and family therapy program. These system enhancements support the Army’s ability to help effective diagnostic and treatment methodologies with the aim of improved mental health. ***FY 2018 Base Plans:***					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283H / *Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
FY 2018 funds will be used to continue to modify the self-service functionality through adding a "view" only feature, which allows enhanced visibility by authorized BH providers. Adds program management module for marriage and family therapy program. These system enhancements will support the Army's ability to help effective diagnostic and treatment methodologies with the aim of improved mental health.					
Accomplishments/Planned Programs Subtotals	0.125	0.080	0.080	-	0.080

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
• BA-1, 0807714HP: *other health Activities*	0.060	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
• BA-1, 0807793DHA: *MHS Tri-Service Information Management/ Information Technology (IM/IT)*	0.074	0.074	0.074	-	0.074	0.074	0.074	0.074	0.074	Continuing	Continuing

Remarks

BAG 104 funding moved to DHA starting on 01 Oct 2015 per FY 2016 POM MOA.
BAG 103 funding moved to DHA starting on 01 Oct 2016 per FY 2017 POM MOA. Moving DCoE to DHA (BA-1, 0807714HP)

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting congressional mandates and program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

FY 2016
Measure: Improved user efficiencies through automation of support/training modules and guidelines.
Baseline: January 2014, 25% user efficiency rating.
Target: March 2018, 90% user efficiency rating.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283H / *Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)*

Source: Audits and analysis performed by Defense Centers of Excellence, Patient-Centered Behavioral Health personnel.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 283J / *Antibiotic Resistance Monitoring and Research (ARMoR-D)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
283J: *Antibiotic Resistance Monitoring and Research (ARMoR-D)*	0.738	0.844	0.878	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Note

In FY 2018, the title of project code 283J is changed from "Multi-Drug Resistant Surveillance Network (MSRN)" to "Antibiotic Resistance Monitoring and Research (ARMoR-D)".

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Antibiotic Resistance Monitoring and Research (ARMoR-D) program includes development projects for Army Service level support. Specifically, the ARMoR-D is the Enterprise Antibiotic Resistant Bacteria program, which collects, characterizes, and conducts epidemiologic surveillance of highly resistant bacteria. ARMoR-D promotes best clinical practices, enhances performance improvement, and focuses infection control strategies.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Antibiotic Resistance Monitoring and Research (ARMoR-D)	0.844	0.878	0.000	-	0.000
Description: ARMoR-D is the Enterprise effort to collect and characterize bacterial isolates to inform best practice, such as patient management and antibiotic selection. ***FY 2016 Accomplishments:*** Continued the development and testing of First System Update of the Phase 3 features of ARMoR-D that were deployed into production during FY 2015. ***FY 2017 Plans:*** Funding is being used to finalize the development and deployment of system updates, which places Phase 3 features into production. These system developments support the Army's ability to assist in the rapid, point-of-care diagnostics for decision-making for antibiotic treatment. ***FY 2018 Base Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.844	0.878	0.000	-	0.000

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283J / *Antibiotic Resistance Monitoring and Research (ARMoR-D)*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	0.565	0.544	0.757	-	0.757	0.775	0.790	0.812	0.830	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Business metrics:
1. Turn-around time from receipt of isolate shipment to initial test results being available on ARMoR-D System.
Current Performance : 2 weeks
Target Performance: 4 days
Data Source: Comparison of isolate receipt date and test result date

2. Time to prepare monthly Antibiogram Report
Current Performance: 8 weeks
Target Performance: 2 weeks
Data Source: Number of days following the end of the month that the report is distributed/posted

3. Antibiogram (or other major product) Report Views
Current Performance: N/A (not currently implemented)
Target Performance: 30 per month
Data Source: Server logs

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 283L / *Pharmacovigilance Defense Application System*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
283L: *Pharmacovigilance Defense Application System*	0.274	0.350	0.400	0.350	-	0.350	0.350	0.350	0.350	0.350	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Pharmacovigilance Defense Application System (PVDAS) provides military providers Defense Patient Safety reports from the Food and Drug Administration (FDA) after a drug´s release to market.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Pharmacovigilance Defense Application System (PVDAS)	0.350	0.400	0.350	-	0.350
Description: The Pharmacovigilance Defense Application System (PVDAS) provides military providers Defense Patient Safety reports from the Food and Drug Administration (FDA) after a drug´s release to market. ***FY 2016 Accomplishments:*** Funding allowed the Pharmacovigilance Center to finalize the process that provides improved information for making Military Health System formulary decisions, better visibility into medical practice enhancing patient safety, and greater access to drug risk/benefit information for military physicians. ***FY 2017 Plans:*** Funds are being used to continue the process that will provide improved information for making Military Health System formulary decisions. This process improvement also provides better visibility into medical practice enhancing patient safety, and greater access to drug risk/benefit information for military physicians. ***FY 2018 Base Plans:*** Funding will be used to start the planning to refine the drug surveillance capabilities and data visualization capabilities of PVDAS.					
Accomplishments/Planned Programs Subtotals	0.350	0.400	0.350	-	0.350

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283L / *Pharmacovigilance Defense Application System*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	1.205	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
• BA-1, 0807714HP: *Other Health Activities*	0.000	0.980	0.974	-	0.974	1.036	2.048	1.134	1.222	Continuing	Continuing
• BA-1, 0807798HP: *Management Headquarters*	1.220	1.500	1.550	-	1.550	1.600	1.650	1.700	1.700	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

There are two metrics we applied. First was to maintain application including software components resolving 100% of all problems resolvable at the Tier 2 level. The resulting measure is that all Tier 2 tickets were resolved as required. The second metric was to provide an operational readiness up time of 98% for the hosted environment, where the application is never inoperable for longer than 3 business days. Hosted environment up time was maintained at 98%.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283M / *Business Intelligence Competency Center (BICC)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
283M: *Business Intelligence Competency Center (BICC)*	1.488	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Business Intelligence Competency Center (BICC) is the business intelligence capability and management processes, focused on providing actionable data at the point of service that facilitates provisioning of actionable information for MTF Commanders, AMEDD Leadership and end users.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Business Intelligence Competency Center (BICC)	0.000	0.000	0.000	-	0.000
Description: The Business Intelligence Competency Center (BICC) is the business intelligence capability and management processes, focused on providing actionable data at the point of service that facilitates provisioning of actionable information for MTF Commanders, AMEDD Leadership and end users. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Base Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000	-	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	0.000	0.000	0.000	-	0.000	0.000	0.000	-	-	Continuing	Continuing
• BA-3, 0807721HP: *Replacement/Modernization*	0.000	0.000	0.000	-	0.000	0.000	0.000	-	-	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283M / *Business Intelligence Competency Center (BICC)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost

Remarks

O&M Funding transferred to DHA starting on 01OCT2015, per FY16POM MOA.

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283N / *Corporate Dental System (CDS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
283N: *Corporate Dental System (CDS)*	0.709	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Corporate Dental System (CDS) is the Dental digital web based DICOM image capture and viewing application.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Corporate Dental System (CDS) ***Description:*** The Corporate Dental System (CDS) is the Dental digital web based DICOM image capture and viewing application. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.	0.000	0.000	-	-	-
Accomplishments/Planned Programs Subtotals	0.000	0.000	-	-	-

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Managment/ Information Technology*	1.438	0.111	0.112	-	0.112	0.114	0.115	0.117	-	Continuing	Continuing
• BA-1, 0807715HP: *Dental Care Activities*	8.758	12.772	13.051	-	13.051	13.386	13.656	13.851	-	Continuing	Continuing
• BA-3, 0807721HP: *Replacement/Modernization*	2.541	0.600	0.600	-	0.600	0.600	0.600	0.600	-	Continuing	Continuing

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283N / *Corporate Dental System (CDS)*

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 283P / *Mobile HealthCare Environment (MHCE)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
283P: *Mobile HealthCare Environment (MHCE)*	0.000	0.362	0.300	0.417	-	0.417	0.331	0.473	0.364	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Mobile HealthCare Environment (MHCE) is the capability of secure, bidirectional messaging and data exchange between patients, providers and clinics using any electronic device.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Mobile HealthCare Environment (MHCE)	0.362	0.300	0.417	-	0.417
Description: The Mobile HealthCare Environment (MHCE) is the capability of secure, bidirectional messaging and data exchange between patients, providers and clinics using any electronic device. ***FY 2016 Accomplishments:*** FY 2016 were utilized to expand the MHCE functionality to include data exchange with other systems, specifically a patient's personal health record, and enterprise systems such as their electronic health record. ***FY 2017 Plans:*** FY 2017 certification/funding are being utilized to continue the expanding of the MHCE functionality deployed in FY 2016, which is the data exchange with other systems, specifically a patient's personal health record, and enterprise systems such as their electronic health record. These system enhancements support the Army's ability to help strengthen the scientific basis for decision-making in patient safety and quality performance within the Military Health System. ***FY 2018 Base Plans:*** FY 2018 certification/funding will be utilized to continue the expanding of the MHCE functionality deployed in FY 2017, which will be the data exchange with other systems, specifically a patient's personal health record, and enterprise systems such as their electronic health record. These system enhancements will support the Army's ability to help strengthen the scientific basis for decision-making in patient safety and quality performance within the Military Health System.					
Accomplishments/Planned Programs Subtotals	0.362	0.300	0.417	-	0.417

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283P / *Mobile HealthCare Environment (MHCE)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	1.285	1.350	1.416	-	1.416	1.477	1.551	1.561	1.571	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 385A / *Integrated Electronic Health Record Inc 1 (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
385A: *Integrated Electronic Health Record Inc 1 (Tri-Service)*	146.417	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Project MDAP/MAIS Code: 465

A. Mission Description and Budget Item Justification

The integrated Electronic Health Record (iEHR) was approved to provide seamless integrated sharing of electronic health data between the DoD and Department of Veterans Affairs (VA).
Commensurate with the OSD AT&L Acquisition Decision Memoranda (ADM), dated July 21, 2013 and January 2, 2014, the former joint DoD and VA iEHR program has been restructured within the DoD to pursue two separate but related healthcare information technology efforts, the DoD Healthcare Management System Modernization (DHMSM) program and a redefined iEHR program. These programs report through the PEO DoD Healthcare Management Systems (DHMS) to the USD (AT&L).

iEHR RDT&E is reported under the program element 0605013 through FY 2013 inclusive, but will be reported under new program element 0605023 for FY 2014 and out.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Integrated Electronic Health Record (iEHR) Inc 1 (Tri-Service)	0.000	0.000	-	-	-
Description: The iEHR primary role is health care delivery services. iEHR is a collaborative effort between the DoD and VA to share Health Care Resources to improve access to, and quality and cost effectiveness of, health care as mandated by law. This investment is deeply embedded in the MHS Enterprise Roadmap as both Departments have need for modernization/ replacement of existing legacy systems. This investment will use a combination of an open architecture approach, and the purchase (in some instances) of GOTS and COTS products. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	-	-	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 385A / *Integrated Electronic Health Record Inc 1 (Tri-Service)*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807793HP: *MHS Tri-Service Information*	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	0.00	0.00

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

None planned.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 386A / *Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
386A: *Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)*	14.464	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The primary goal of the VLER Health initiative is to enable the secure sharing of health information (i.e., demographic and clinical data) between DoD and external Federal and private sector partners which meets Meaningful Use (MU) requirements to improve healthcare quality, safety, and efficiency. By electronically sharing health information using national standards, that information can support tracking key clinical conditions, communicating that information to better coordinate care, and engaging patients in their own care. The VLER Health initiative provides clinicians with the most up-to-date information, potentially reducing redundant diagnostic tests, medical errors, paperwork and handling, and overall healthcare costs. These benefits, in turn, align with the MHS quadruple aim by ensuring that the military force is medically ready to deploy; the military beneficiary population remains healthy through focused prevention; patient care is convenient, equitable, safe, and of the highest quality; and the total cost of healthcare is reduced through the reduction of waste and focus on quality.

VLER Health funding will be reflected in the Integrated Electronic Health Record Program Element 0605023 in FY 2014 and out.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service) ***Description:*** Work with Department of Veterans Affairs (VA), Department of Health & Human Services (HHS), and Private Sector to expand VLER. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.	0.000	0.000	-	-	-
Accomplishments/Planned Programs Subtotals	0.000	0.000	-	-	-

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807793HP: *MHS Tri-Service Information*	-	-	-	-	-	-	-	-	-		

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 386A / *Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 423A / *Defense Center of Excellence (FHP&RP)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
423A: *Defense Center of Excellence (FHP&RP)*	3.464	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Note

In FY15, transferred from FHP&R (Project Code 423A) to Army (Project Code 423B).

A. Mission Description and Budget Item Justification

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE) is a United States Department of Defense (DoD) organization that provides guidance across DoD programs related to psychological health (PH) and traumatic brain injury (TBI) issues. The organization's mission statement is: "DCoE assesses, validates, oversees and facilitates prevention, resilience, identification, treatment, outreach, rehabilitation, and reintegration programs for PH and TBI to ensure the Department of Defense meets the needs of the USA's military communities, warriors and families." DCoE focuses on education and training; clinical care; prevention; research; and service member, family and community outreach. In collaboration with the Department of Veterans Affairs, the organization supports the Department of Defense's commitment of caring for service members from the time they enter service and throughout the completion of their service. DCoE also seeks to mitigate the stigma that still deters some from reaching out for help for problems such as post-traumatic stress disorder and TBI. The organization has a leadership role in collaborating with a national network of external entities[1] including non-profit organizations,[2] other DoD agencies, academia, Congress,[3] military services and other federal agencies.[4] Public health service and civil service workers, including personnel from the Department of Veterans Affairs and individuals from all the military services as well as contract personnel comprise the staff of DCoE. DCoE's goals include providing the necessary resources to facilitate the care of service members who experience TBI or PH concerns and ensuring that appropriate standards of care exist and are maintained across the Department of Defense. DCoE seeks to create, identify and share best practices, conducting necessary pilot or demonstration projects to better inform quality standards when best practices or evidence based recommendations are not readily available. Other DCoE goals include ensuring that program standards are executed and quality is consistent and creating a system in which individuals across the United States expect and receive the same level and quality of service regardless of their service branch, component, rank or geographic location. DCoE comprises eight directorates and six component centers responsible for TBI/PH issues. These DCoE entities execute programs, provide clinical care, conduct research, identify and share best practices and provide strategic planning for PH and TBI across the DoD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Defense Center Of Excellence (FHP&RP)	0.000	0.000	-	-	-
Description: DCoE programs and products are developed to drive innovation across the continuum of care by identifying treatment options and other clinical and research methods that deliver superior outcomes. Products range from tools customized for health care providers to electronic resources for service members and families.					
FY 2016 Accomplishments:					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 423A / *Defense Center of Excellence (FHP&RP)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	-	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 423B / *Defense Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
423B: *Defense Center of Excellence (Army)*	0.996	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Note

Transferred from FHP&R (Project Code 423A) to Army (Project Code 423B) in FY 2015.
Transferred from Army (Project Code 423B) to DHA (Project Code 423C) in FY 2017.

A. Mission Description and Budget Item Justification

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury is administratively managed under the US Army Medical Command (MEDCOM) that provides guidance across DoD programs related to psychological health (PH) and traumatic brain injury (TBI) issues. DCoE focuses on education and training; clinical care; prevention; research; and Service Member, Family, and community outreach. In collaboration with the Department of Veterans Affairs, DCoE supports the DoD's commitment of caring for Service members from the time they enter service and throughout the completion of their service. DCoE also seeks to mitigate the stigma that still deters some from reaching out for help for problems such as post-traumatic stress disorder and TBI. The organization has a leadership role in collaborating with a national network of external entities to include: 1- Non-profit organizations, 2- Other DoD agencies, academia, and Congress, 3- Military services and other federal agencies and, 4- Public Health Service and civil service workers, to include personnel from the Department of Veterans Affairs and individuals from all military services as well as contractor personnel assigned to DCoE. DCoE's goals include providing the necessary resources to facilitate the care of Service members who experience TBI and/or PH concerns and ensuring that appropriate standards of care exist and are maintained across the DoD. DCoE seeks to create, identify, and share best practices; conducting necessary pilot or demonstration projects to better inform quality standards when best practices or evidence-based recommendations are not available. Additional goals include ensuring that program standards are executed and quality is consistent for all individuals throughout the United States so that they receive the same level and quality of service regardless of service branch, component, rank, or location. DCoE is comprised of a HQs element and three component centers responsible for PH/TBI issues. These DCoE directorates and centers execute programs, provide clinical care, conduct research, and identify and share best practices and provide strategic planning for all PH and TBI throughout the DoD. Management of IMIT funds are transferred from Army to DHA effective in FY 2017.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Defense Center of Excellence (Army)	0.000	0.000	0.000	-	0.000
Description: DCoE programs and products are developed and implemented to drive innovation across the continuum of care by identifying treatment options and other clinical and research methods that deliver superior healthcare outcomes. Products range from tools customized for healthcare providers to electronic resources such as online games and mobile apps for Service Members and their Families.					
FY 2016 Accomplishments:					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 423B / *Defense Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
FY 2016 funds were used to complete the development and transition to sustainment for the electronic capabilities listed above. The T2 toolkit and its sub-components were more fully developed in order to allow for further collaboration and remote access to tools. RDT&E funding were utilized to continue development of mobile applications, 3D games, websites, and other applications. In addition, the DHCC FIRST STEPS module were continued to evolve and develop capabilities to tailor reporting, track data by individual Service, and monitor conditions such as smoking cessation and obesity/weight management. This program also added healthcare facilitators in behavioral activation and motivational interviewing techniques with patients. ***FY 2017 Plans:*** Management of funds is transferred from Army (423B) to DHA (423C) effective in FY 2017. ***FY 2018 Base Plans:*** No funding programmed.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000	-	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	-	-	-	-	-	-	-	-	-		
• BA-1, 0807724HP: *Military Unique - Other Medical*	-	-	-	-	-	-	-	-	-		

Remarks

O&M Dollars were transferred back to DCoE during the 16PB BCP, which took effect on 01OCT2015.

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements. Program cost, schedule and performance are measured periodically using a systematic approach.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 423C / *Defense Center of Excellence (T2T/ PBH TERM) (DHA)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
423C: *Defense Center of Excellence (T2T/PBH TERM) (DHA)*	0.000	0.000	1.369	1.395	-	1.395	1.422	1.450	1.478	1.509	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE) provides the Military Health System with current and emerging psychological health and traumatic brain injury clinical and educational information. DCOE identifies gaps and prioritize needs in psychological health and TBI research, and then translate that research into clinical practice to improve patient outcomes.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Defense Center of Excellence (DHA) T2T and PBH TERM	0.000	1.369	1.395	-	1.395
Description: DCoE programs and products are developed and implemented to drive innovation across the continuum of care by identifying treatment options and other clinical and research methods that deliver superior healthcare outcomes. Products range from tools customized for healthcare providers to electronic resources such as online games and mobile apps for Service Members and their Families. Telehealth and Technology Toolkit (T2T):This project will organize a toolkit of components in the areas of PH and telehealth that can be used both within and outside DoD. The focus of the toolkit is NOT to develop duplicative components, but allow room for collaboration and remote access to tools. The T2 Toolkit consists of mobile applications, 3-Dimensional applications (apps) , and supporting websites. These applications will combine to create a system that covers many areas of Psychological Health (PH) for the Department of Defense, family members. Psychological and Behavioral Health – Tools for Evaluation, Risk and Management (PBH-TERM) is a web-based psychological and behavioral health (BH) information technology application which supports evidence-based, standardized and integrated BH initiatives and program evaluation.					
FY 2016 Accomplishments: Funding and accomplishments are reported under the DCOE (Army) project codes. Funding and management was transferred from Army to DHA beginning in FY2017.					
FY 2017 Plans:					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 423C / *Defense Center of Excellence (T2T/ PBH TERM) (DHA)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
T2T funding will be used to develop and deploy 3-4 mobile apps per year and the deployment of mobile apps with wearables. Other funding will be used in the sustainment of mobile apps, the sustainment of the T2health.dcoe.mil website, and the retirement of designated mobile apps. PBH TERM: FY17 RDT&E funding ($135K) will be used for requirements which will be used in support of DoD Strategic Management Plan (SMP) Objective 3 – Increased Health Information Technology (HIT) Effectiveness and DHA Strategic Objective IP8 – Improve Comprehensive Primary Care. Other O&M funding ($65K) in support of PBH TERM system for improved HIT tools for Behavioral HealthCare Facilitators (BHCF), social workers, healthcare providers, and health system program managers to enable better case tracking, warnings for patient severity data, caseload management, and reduction of costs. ***FY 2018 Base Plans:*** FY18 plans to continue the development and deployment of 3-4 mobile applications each year. Remaining funding will be used for application sustainment of the mobile applications, T2health.dcoe.mil website, and the retirement of specific mobile applications. PBH TERM funding will be used to support the DoD Strategic Management Plan Objective 3 – Increased HIT Effectiveness and DHA Strategic Objective IP8 – Improve Comprehensive Primary Care.					
Accomplishments/Planned Programs Subtotals	0.000	1.369	1.395	-	1.395

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information Management/ Information Technology (IM/IT)*	0.000	2.159	2.198	-	2.198	2.239	0.000	0.000	0.000	Continuing	Continuing
• BA-1, 0807724DHA: *Military Unique Requirements - Other Medical - Health Care*	0.000	3.733	3.768	-	3.768	3.808	6.147	6.270	6.458	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 423C / *Defense Center of Excellence (T2T/ PBH TERM) (DHA)*

E. Performance Metrics

Each program establishes performance measurements. Program cost, schedule and performance are measured periodically using a systematic approach.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*				Project (Number/Name) 435A / *NICOE Continuity Management Tool*			
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
435A: *NICOE Continuity Management Tool*	2.855	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The NICoE Continuity Management Tool (NCMT) is a business intelligence tool to perform healthcare modeling and analysis of NICoE activities.

Major capabilities defined by the NICoE in Jun 2009 and refined in Jun 2010 prior to the program procurement in Sep 2010, are subsystems that make up the NCMT end-to-end system, and were prioritized in the following order: Continuity Management Subsystem, Scheduling Subsystem, Clinical Subsystem, Research Subsystem, Training and Education Subsystem, Administration Subsystem.

Continuity Management Subsystem: Records every interaction with a particular Warrior and his or her Family as one entity to manage initial contact, referral, screening, intake, pre-admission, admission, discharge and follow-up processes.

Scheduling Subsystem: Captures, organizes, displays the complex schedules of the NICoE. Used to manage patient appointments, the utilization of facility resources including treatment rooms, modalities, provider staff and support staff.

Clinical Subsystem: A clinical application and clinical database that includes the functions that allow the user to store, classify, analyze, retrieve, interpret, present clinical data. Allows the visualization of all of the various components of the patient's health record: radiology, pathology, lab results, neurological assessments, etc.

Research Subsystem: Consists of the research database and the applications that allow the user to store, classify, analyze, retrieve, interpret, present data. Allows NICoE to aggregate data from disparate systems, both within the NICoE and from partner organizations, helping the research move faster, with more agility, and with purpose and direction supported by validated facts. Allows researchers to address many data challenges from a single system and transforms the way they do research.

Training and Education Subsystem: Provides the ability to share relevant research, diagnosis, treatment information with authorized users.

Administration Subsystem: Provides the ability to manage a portfolio of projects related to continuity of care, clinical operations, research, training and education functions in the NICoE.

The NCMT is supported by Three Contracts: Hosting (Provides Hardware, Software, Maintenance), System Integration (Implements NICoE Functional Requirements, Turns NICoE Ideas and Goals into Computer Screens, Templates, Applications – Capabilities) and Decision Support (Acquisition Management, Requirements Definition, Implementation Planning).
The NICoE's missions are to:

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 435A / *NICOE Continuity Management Tool*

1) Explore novel, promising, and futuristic solutions to the complex spectrum of combat brain injury from TBI to posttraumatic stress disorder (PTSD) and other psychological injuries;

2) Ensure – through continuous outreach and high quality health care – that America embraces those who have served and sacrificed so much on its behalf; and

3) Train the next generation of providers in the most effective approaches to prevention, detection, and treatment options.

Currently the established AHLTA specification does not adequately support the specialized care and continuity management integration necessary to support NICoE clinical operations and research. Additionally, AHLTA does not support the data mining and pattern recognition requirements of the NICoE.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: NICOE Continuity Management Tool	0.000	0.000	-	-	-
Description: The NCMT is a tool designed to perform healthcare modeling and analysis of NICoE activities. Major capabilities include Continuity Management, Scheduling, Clinical Database, Research Database, Training and Education, and Administration. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	-	-	-

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• 4187 807783: *NCMT*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
• 4187 807781: *NCMT*	4.107	4.259	4.332	-	4.332	-	-	-	-	Continuing	Continuing
• 1690 807781: *HEIS*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
• 4859 807781: *JMED*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
• 4940 807781: *JTFCMI*	41.610	42.395	43.267	-	43.267	-	-	-	-	Continuing	Continuing
• 4940 807720: *JTFCMI*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
• 4273 807781: *Engineering and Deployment*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 435A / *NICOE Continuity Management Tool*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• 4280 807721: *Engineering and Deployment*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
• 4361 807781: *IA Operational Resiliency*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
• 4126 807781: *Computer Network Defense*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
• 4111 807781: *Computer Network Defense*	0.482	0.492	0.502	-	0.502	-	-	-	-	Continuing	Continuing
• 4165 807781: *Computer Network Defense*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
• 4177 807781: *Computer Network Defense*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
• 4364 807781: *Workforce Development*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

This requirement is currently contracted through the USA Medical Research Activity. The vender is Evolvent Technologies Inc.

E. Performance Metrics

This performance metrics or milestones shall include, but is not limited to:

Coordination with Government representatives
Review, evaluation and transition of current support services
Transition of historic data to new contractor system
Government-approved training and certification process
Transfer of hardware warranties and software licenses
Transfer of all System/Tool documentation to include, at a minimum: user manuals, system administration manuals, training materials, disaster recovery manual, requirements traceability matrix, configuration control documents and all other documents required to operate, maintain and administer systems and tools
If another contractor follows this contractor with work related to this work, this contractor will provide any developed source code (compiled and uncompiled, including all versions, maintenance updates and patches) with written instructions for the source code on which this contractor has worked, so that an experienced software

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 435A / *NICOE Continuity Management Tool*

engineer, previously not familiar with the source code can understand and efficiently work with the source code. In addition, this contractor will provide for 30 days, a software engineer (or person of comparable work level) with significant experience working with the source code, to assist the new contractor
Orientation phase and program to introduce Government personnel, programs, and users to the Contractor's team, tools, methodologies, and business processes
Disposition of Contractor purchased Government owned assets, including facilities, equipment, furniture, phone lines, computer equipment, etc.
Transfer of Government Furnished Equipment (GFE) and Government Furnished Information (GFI), and GFE inventory management assistance
Applicable TMA debriefing and personnel out-processing procedures
Turn-in of all government keys, ID/access cards, and security codes.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 446A / *Disability Mediation Service (DMS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
446A: *Disability Mediation Service (DMS)*	0.887	0.399	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Disability Mediation Service (DMS): The VTA (Veteran's Tracking Application) has been the primary system to track, record, and report data for the IDES (Integrated Disability Evaluation System) process. The VTA is scheduled to sun-set, by VA (Veterans Affairs), and the data is being moved to another application. Migration of VTA to another application creates the requirement to allow data exchange between Service non-medical case management and new VA DES (Disability Evaluation System) IT application. The BEC (Benefits Executive Council) is looking to create a DMS (Disability Mediation Service), which is an integrator between the Services and VA.
The DMS will facilitate the improvement of non-medical case management tracking and IDES data/information management. It will eliminate redundant data entry within DoD (Department of Defense), improving data quality by capturing more data for operational reporting from the Services and WCP, decrease backlog by eliminating data entry duplication, and minimize impact to DoD Services by allowing the Services to continue using their existing/planned systems without requiring retraining on a new applications.
The DMS will be created from existing technology. It will provide a mediation service to help isolate each system from changes and uniqueness in the other systems and allow the Services and WCP to report and drill down on data that we capture during the exchange. This IT solution will not replace current DoD systems, but will require some modifications and enhancements to those systems to support the date exchange. WCP will support development costs for these efforts. Services will assume responsibility and POM costs for modifications, enhancements, and maintenance in the out years."

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Disability Mediation Service (DMS)	0.399	0.000	0.000	-	0.000
Description: The VTA (Veteran's Tracking Application) has been the primary system to track, record, and report data for the IDES (Integrated Disability Evaluation System) process. The VTA is scheduled to sun-set, by VA (Veterans Affairs), and the data is being moved to another application. Migration of VTA to another application creates the requirement to allow data exchange between Service non-medical case management and new VA DES (Disability Evaluation System) IT application. The BEC (Benefits Executive Council) is looking to create a DMS (Disability Mediation Service), which is an integrator between the Services and VA. The DMS will facilitate the improvement of non-medical case management tracking and IDES data/information management. It will eliminate redundant data entry within DoD (Department of Defense), improving data quality by capturing more data for operational reporting from the Services and WCP, decrease backlog by eliminating data entry duplication, and minimize impact to DoD Services by allowing the Services to continue using their existing/planned systems without requiring retraining on a new applications. The DMS will be created from existing technology. It will provide a mediation service to help isolate each system from changes and uniqueness in the other systems and allow the Services and WCP to report and drill down on					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 446A / *Disability Mediation Service (DMS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
data that we capture during the exchange. This IT solution will not replace current DoD systems, but will require some modifications and enhancements to those systems to support the date exchange. WCP will support development costs for these efforts. Services will assume responsibility and POM costs for modifications, enhancements, and maintenance in the out years." ***FY 2016 Accomplishments:*** FY16 accomplishments include the refinement and further development of JDES-IT functional requirements and initiating the identification and documentation for "As Is" and "To Be" business workflows. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Base Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.399	0.000	0.000	-	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 480B / *Defense Medical Human Resources System (Internet) (DMHRSi) (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480B: *Defense Medical Human Resources System (Internet) (DMHRSi) (Tri-Service)*	0.585	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Defense Medical Human Resources System – internet (DMHRSi) enables the Services to standardize and optimize the management of human resource assets across the Military Health System (MHS). DMHRSi is a Web-based system that enables improved decision making by facilitating the collection and analysis of critical human resource data. It standardizes medical human resource information and provides enterprise-wide visibility for all categories of human resources (Active Duty, Reserve, Guard, civilian, contractor, and volunteer medical personnel); improves reporting of medical personnel readiness and; streamlines business processes to improve data quality for management decision making and managing the business; provides Tri-Service visibility of associated labor costs and is source for personnel cost data.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Defense Medical Human Resources System (internet) (DMHRSi) (Tri-Service)	0.000	0.000	0.000	-	0.000
Description: The Defense Medical Human Resources System – internet (DMHRSi) enables the Services to standardize and optimize the management of human resource assets across the Military Health System (MHS). DMHRSi is a Web-based system that enables improved decision making by facilitating the collection and analysis of critical human resource data. It standardizes medical human resource information and provides enterprise-wide visibility for all categories of human resources (Active Duty, Reserve, Guard, civilian, contractor, and volunteer medical personnel); improves reporting of medical personnel readiness and; streamlines business processes to improve data quality for management decision making and managing the business; provides Tri-Service visibility of associated labor costs and is source for personnel cost data. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Base Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000	-	0.000

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480B / *Defense Medical Human Resources System (Internet) (DMHRSi) (Tri-Service)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 480C / *Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480C: *Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)*	13.710	1.780	2.326	2.363	-	2.363	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Purpose: DMLSS provides a standard Department of Defense (DoD) medical logistics system. DMLSS suite of applications provides healthcare driven capability to support medical logistics needs for critical medical commodities - pharmaceuticals and medical/surgical supplies across continuum of care from the battlefield to tertiary care at a major DoD military treatment facility (MTF). This capability is enabled by the partnership of the Defense Logistics Agency (DLA) – Troop Support Medical and the Military Health System (MHS) providing an industry to practitioner supply chain for the medical commodity. The DMLSS DLA Wholesale (DMLSS-W) applications are funded by DLA while the garrison medical treatment facilities and theater applications are funded by the Defense Health Program.

Goal: The current DMLSS system provides full spectrum capability for medical logistics management.

Benefits: Stock control, Prime Vendor operations, preparation of procurement documents, research and price comparison for products, property accounting, biomedical maintenance operations, capital equipment, property management, inventory, and a facility management application that supports the operations of a fixed MTF physical plant and supports the Joint Commission accreditation requirements. DMLSS, in coordination with Joint Operational Medicine Information Systems (JOMIS), is providing to Services and Combatant Commanders the logistics capabilities necessary to rapidly project and sustain joint medical capabilities for medical logistics management of theater medical materiel operations. Products deployed to the theater include the DMLSS Customer Assistance Module (DCAM), a medical logistics ordering tool that allows users to view their supplier's catalog and generate electronic orders. Primarily focused on the theater environment, DCAM automates the Class VIII supply process at lower levels of care, and allows non-logisticians to electronically exchange catalog, order, and status information with their supply activity. The Joint Medical Asset Repository (JMAR) provides Enterprise asset visibility and business intelligence tool. JMAR is web-based application that provides Enterprise medical logistics (MEDLOG) asset visibility, transactional data and business intelligence (BI) and Decision Support (DS) across the MHS.

Stakeholders: MHS and DLA troop support. Customers: medical logisticians, biomedical technicians, clinical staff, and facilities management personnel in MTFs

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)	1.780	2.326	2.363	-	2.363
Description: Development, integration and modernization of DMLSS modules.					
FY 2016 Accomplishments: Used to continue the development of a federated regional logistics capability. They will also be used to update the Medical Vendor product and pricing management routines. They will also be used to continue the					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480C / *Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
development of enhanced enterprise lifecycle/equipment management functionality. They will also be used to continue to enhance functionality identified during the Prime Vendor Gen IV enhancements. ***FY 2017 Plans:*** Modernization funds will be used to begin the development of a secure drug and medical device supply chain traceability capability. They will also be used to begin the development of a patient safety / FDA recall alerts medical material quality control capability. They will also be used to continue to update the Medical Vendor product and pricing management routines. ***FY 2018 Base Plans:*** Continue the development of a secure drug and medical device supply chain traceability capability. And, also continue the development of a patient safety / FDA recall alerts medical material quality control capability. They will also be used to continue to update the Medical Vendor product and pricing management routines.					
Accomplishments/Planned Programs Subtotals	1.780	2.326	2.363	-	2.363

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	31.007	35.014	35.624	-	35.624	36.233	35.952	35.797	36.508	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources. Performance metrics for specific projects may be viewed at the OMB Federal IT Dashboard website.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480D / *Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480D: *Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)*	8.052	0.000	6.140	6.025	-	6.025	5.559	6.416	6.902	7.040	Continuing	Continuing

A. Mission Description and Budget Item Justification

Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) is a comprehensive, automated information system that provides a single point for assembling, comparing, using, evaluating, and storing occupational personnel exposure information, workplace environmental monitoring data, personnel protective equipment usage data, observation of work practices data, and employee health hazard educational data. DOEHRS-IH will provide for the definition, collection and analysis platform to generate and maintain a Service Member´s Longitudinal Exposure Record. DOEHRS-IH will describe the exposure assessment, identify similar exposure groups, establish a longitudinal exposure record baseline to facilitate post-deployment follow-up, and provide information to enable exposure-based medical surveillance and risk reduction.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)	0.000	6.140	6.025	-	6.025
Description: Configure, enhance, and interface DOEHRS-IH modules.					
FY 2016 Accomplishments: No Funding Programmed.					
FY 2017 Plans: Modernization funds will be used to continue to address a backlog of Critical User Enhancements that will dramatically increase the ease of use and data integrity of the DOEHRS-IH application. They will also be used to develop configuration of HazMat Product Hazard Data - Material Safety Data Sheets (MSDS), as mandated by Occupational Safety and Health Administration (OSHA) 29 CFR 1910.120.					
FY 2018 Base Plans: Modernization funds will be used to continue to address a backlog of Critical User Enhancements that will dramatically increase the ease of use and data integrity of the DOEHRS-IH application. They will also be used					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480D / *Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
to implement an interface to DOEHRS-Hearing Conservation (HC) to support an automated capability to rapidly access, extract and incorporate information from DOEHRS-HC. This will assist occupational and environmental health (OEH) personnel in providing guidance in the prevention and treatment of noise exposures and injuries. In addition this funding will support a Data Entry User Interface, which will support a new graphical user interface (GUI) that enables the user to more efficiently and accurately enter data in the system and retrieve information to determine potential exposures.					
Accomplishments/Planned Programs Subtotals	0.000	6.140	6.025	-	6.025

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	8.290	12.262	14.835	-	14.835	14.886	15.864	17.030	17.371	Continuing	Continuing
• BA-3, 0807721DHA: *Replacement/Modernization*	0.113	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources. Performance metrics for specific projects may be viewed at the OMB Federal IT Dashboard website.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 480F / *Executive Information/Decision Support (EI/DS) (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480F: *Executive Information/ Decision Support (EI/DS) (Tri-Service)*	5.936	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

EI/DS was comprised of a central datamart Military Health System Data Repository (MDR) and several smaller datamarts: MHS Management Analysis and Reporting Tool (M2), Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE), and Purchased Care Operations Systems -TRICARE Encounter Data (TED) & Patient Encounter Processing and Reporting (PEPR). Many of these operate within a Business Objects XI (BOXI) environment. EI/DS manages receipt, processing, and storage of over 155 terabytes of data from both Military Treatment Facilities (MTF) and the TRICARE purchased care network systems. These data include inpatient dispositions, outpatient encounters, laboratory, radiology, and pharmacy workload, TRICARE network patient encounter records, TRICARE mail order pharmacy patient encounter records, beneficiary demographics, MTF workload and cost information, eligibility and enrollment, Pharmacy Data Transaction Service data, customer satisfaction surveys, and data associated with the Wounded Warrior care. EI/DS provides centralized collection, storage and availability of data, in various data marts, to managers, clinicians, and analysts for the management of the business of health care. EI/DS has been broken apart into 4 separate initiatives beginning in FY17. These initiatives are (1) ESSENCE), (2) PHIMT, (3) CEIS, and (PCOS).

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Executive Information/Decision Support (EI/DS) (Tri-Service) ***Description:*** Development, modernization, upgrades and testing for various EI/DS modules. EI/DS has been broken apart into 4 separate initiatives beginning in FY17. These initiatives are (1) ESSENCE), (2) PHIMT, (3) CEIS, and (PCOS). ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Base Plans:*** No Funding Programmed.	0.000	0.000	0.000	-	0.000
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000	-	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480F / *Executive Information/Decision Support (EI/DS) (Tri-Service)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

Not applicable.

E. Performance Metrics

Not applicable.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 480G / *Health Artifact and Image Management Solution (HAIMS) (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480G: *Health Artifact and Image Management Solution (HAIMS) (Tri-Service)*	8.123	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Health Artifact and Image Management Solution (HAIMS) enables the DoD and the VA healthcare providers to have global access and awareness of artifacts and images (A&I) generated during the healthcare delivery process. HAIMS will provide the new capability for users throughout the MHS to be aware and have access to A&I that have been registered with the central “system”, currently on local workstations and Military Treatment Facility (MTF) Picture Archive and Communications Systems (PACs). As patients move through the continuum of care from Continental United States to Theater and then return to DoD sustaining bases facilities, healthcare A&I moves seamlessly and simultaneously with the patient. This advances several MHS strategy initiatives such as achievement of paperless record, global access of Wounded Warrior scanned documents, and an alternative to finding storage space for paper records of merging MTFs. HAIMS will supply access to VHA and other external A&I both inside and outside the Military Health System (MHS) Electronic Health Record (EHR).

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Health Artifact and Image Management Solution (HAIMS) (Tri-Service)	0.000	0.000	0.000	-	0.000
Description: Integrate new functionality into HAIMS. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Base Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000	-	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	17.575	25.634	25.298	-	25.298	22.398	22.919	23.377	31.663	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480G / *Health Artifact and Image Management Solution (HAIMS) (Tri-Service)*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-3, 0807721DHA: *Replacement/Modernization*	9.500	12.500	12.604	-	12.604	13.732	14.007	14.287	6.755	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 480K / *Integrated Federal Health Registry Framework (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480K: *Integrated Federal Health Registry Framework (Tri-Service)*	3.652	0.413	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The purpose of an integrated Federal Health Registry capability is to provide a viable solution to fulfill a critical need for improved sharing and exchange of Service member and Veteran health information and data between the Department of Defense - Health Affairs and the Department of Veterans Affairs Veterans Health Administration communities of interest (COIs) as mandated in Section 1635 of the 2008 National Defense Authorization Act (NDAA, 2008). This ability to share and exchange vital health care data between the respective specialties of care is essential to conduct longitudinal analyses necessary to improve patient care and quality of life outcomes. To maximize efficiencies and most effectively meet the needs of the functional communities, the Centers of Excellence (CoEs) have developed a consolidated framework solution for an integrated Federal Health Registry capability. This effort provides a comprehensive solution that meets the specialty care needs of each of the Services and Veteran Affairs that are represented by the Joint DoD and VA CoEs, (Army-Extremity Trauma and Amputation Center of Excellence; Defense Health Agency-Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury; Navy-DoD/VA Vision Center of Excellence; Air Force-Hearing Center of Excellence; and National Capital Region-National Intrepid Center of Excellence). Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: integrated Health Registry Framework (Tri-Service) ***Description:*** Develop, integrate and test a common registry. ***FY 2016 Accomplishments:*** FY16 accomplishments include: completed System Integration Testing (SIT), completed the development of iHRF version 1.0 based on the SIT results. Yet to complete with FY16 funding are the Interoperability (IOP) testing and Operational Test and Evaluation (OT&E). ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Base Plans:*** No Funding Programmed.	0.413	0.000	0.000	-	0.000
Accomplishments/Planned Programs Subtotals	0.413	0.000	0.000	-	0.000

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480K / *Integrated Federal Health Registry Framework (Tri-Service)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	2.838	2.865	2.913	-	2.913	0.000	0.000	0.000	0.000	Continuing	Continuing
• BA-3, 0807721DHA: *Replacement/Modernization*	0.015	0.094	0.066	-	0.066	0.000	0.000	0.000	0.000	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Program cost, schedule and performance are measured periodically using a systematic approach as required for Major Automated Information Systems (MAIS) per DoD Directives and Instructions.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480M / *Theather Medical Information Program - Joint (TMIP-J) (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480M: *Theather Medical Information Program - Joint (TMIP-J) (Tri-Service)*	28.731	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Theater Medical Information Program - Joint (TMIP-J) integrates components of the Military Health System sustaining base systems and the Services´ medical information systems to ensure timely interoperable medical support for mobilization, deployment and sustainment of all Theater and deployed forces in support of any mission. TMIP-J enhances the clinical care and information capture at all levels of care in Theater, transmits critical information to the Theater Commander, the evacuation chain for combat and non-combat casualties, and forges the theater links of the longitudinal health record to the sustaining base and the Department of Veterans Affairs. TMIP-J is the medical component of the Global Combat Support System. TMIP-J provides information at the point of care and to the Theater tactical and strategic decision makers through efficient, reliable data capture, and data transmission to a centralized Theater database. This delivers TMIP-J´s four pillars of information support through the electronic health record, integrated medical logistics, patient movement and tracking, and medical command and control through data aggregation, reporting and analysis tools for trend analysis and situational awareness. TMIP-J fulfills the premise of "Train as you fight" through the integration of components which are identical or analogous to systems from the sustaining base. TMIP-J adapts and integrates these systems to specific Theater requirements and assures their availability in the no- and low- communications settings of the deployed environment through store and forward capture and transmission technology.

TMIP-J RDT&E is reported under the program element 0605013 through FY 2013 inclusive, but will be reported under new program element 0605023 for FY 2014 and out.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Theather Medical Information Program - Joint (TMIP-J) (Tri-Service)	0.000	0.000	-	-	-
Description: The Theater Medical Information Program - Joint (TMIP-J) integrates components of the Military Health System sustaining base systems and the Services´ medical information systems to ensure timely interoperable medical support for mobilization, deployment and sustainment of all Theater and deployed forces in support of any mission. TMIP-J enhances the clinical care and information capture at all levels of care in Theater, transmits critical information to the Theater Commander, the evacuation chain for combat and non-combat casualties, and forges the theater links of the longitudinal health record to the sustaining base and the Department of Veterans Affairs. TMIP-J is the medical component of the Global Combat Support System. TMIP-J provides information at the point of care and to the Theater tactical and strategic decision makers through efficient, reliable data capture, and data transmission to a centralized Theater database. This delivers TMIP-J ´s four pillars of information support through the electronic health record, integrated medical logistics, patient movement and tracking, and medical command and control through data aggregation, reporting and analysis					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480M / *Theather Medical Information Program - Joint (TMIP-J) (Tri-Service)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
tools for trend analysis and situational awareness. TMIP-J fulfills the premise of "Train as you fight" through the integration of components which are identical or analogous to systems from the sustaining base. TMIP-J adapts and integrates these systems to specific Theater requirements and assures their availability in the no- and low-communications settings of the deployed environment through store and forward capture and transmission technology. TMIP-J RDT&E is reported under the program element 0605013 through FY 2013 inclusive, but will be reported under new program element 0605023 for FY 2014 and out. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	-	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 480P / *Other Related Technical Activities (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480P: *Other Related Technical Activities (Tri-Service)*	4.139	0.000	1.683	3.500	-	3.500	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Other Related Technical Activities includes funding for Information Technology activities common to multiple or all Tri-Service systems/programs and cannot be associated with any one individual Tri-Service initiative, which includes enterprise Messaging and other common IT services requirements. Additionally, in standing up the new Defense Health Agency (DHA) on October 1, 2013, one of the signature efforts of the reorganization is the establishment of a Shared Services model for the delivery of enterprise-wide support services to the Military Health System (MHS). One of the five shared services in DHA is Health Information Technology (HIT). The MHS Shared Services Portfolio Rationalization (MHS SSPR) is an initiative to capture those costs which need to be called out separately to implement the share services HIT portfolio rationalization.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Other Related Technical Activities (Tri-Service) ***Description:*** Activities common to multiple or all Tri-Service systems/programs and cannot be associated with any one individual Tri-Service initiative, which includes MHS SSPR. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** FY17 plans are to support funding of the Health Information Technology Shared Services investment. ***FY 2018 Base Plans:*** In FY18, funding requirements will continue to support the Health Information Technology Shared Services investment.	0.000	1.683	3.500	-	3.500
Accomplishments/Planned Programs Subtotals	0.000	1.683	3.500	-	3.500

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-3, 0807721DHA: *Replacement/Modernization*	0.000	2.310	2.730	-	2.730	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480P / *Other Related Technical Activities (Tri-Service)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each activity establishes performance measurements. Program cost, schedule and performance are measured periodically using a systematic approach. Since this is an enterprise initiative which crosses mutliple initiatives, performance metrics of the common activities are part of and/or contributing factors in the measurement of the performacne metrics of the individual initiatives.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 480Y / *Clinical Case Management (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480Y: *Clinical Case Management (Tri-Service)*	2.925	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Provides a seamless view of the care and the health of the patient from the origin of injury or illness to the end of the need for that episode of care. It will capture relevant events, information, documents and other data to support the overall improvement of the patient's condition utilizing medical Case Management practices. It will provide the ability to collect clinical information in support of the medical Case Manager's mission and will provide information gathered to MTFs and MSCSs.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Clinical Case Management (Tri-Service) ***Description:*** Provides a seamless view of the care and the health of the patient from the origin of injury or illness to the end of the need for that episode of care. It will capture relevant events, information, documents and other data to support the overall improvement of the patient's condition utilizing medical Case Management practices. It will provide the ability to collect clinical information in support of the medical Case Manager's mission and will provide information gathered to MTFs and MSCSs. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Base Plans:*** No Funding Programmed.	0.000	0.000	0.000	-	0.000
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000	-	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480Y / *Clinical Case Management (Tri-Service)*

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 481A / *Theather Enterprise Wide Logistics System (TEWLS) Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
481A: *Theather Enterprise Wide Logistics System (TEWLS) Tri-Service)*	5.127	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Theater Enterprise-Wide Logistics System (TEWLS) supports critical medical logistics warfighter requirements in a net-centric environment. It ties the national, regional, and deployed units into a single business environment. It creates the necessary links for planners, commercial partners, and AMEDD logisticians to accomplish essential care in the theater through a single customer facing portal. It removes disparate data and replaces it with a single instance of actionable data. TEWLS supports today ´s modern, non-contiguous battlefield at the regional, COCOM, and Service levels by leveraging emerging Medical Materiel Executive Agency and Theater Lead Agent infrastructure concepts to manage the entire medical supply chain from the industrial base to the end user.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Theather Enterprise Wide Logistics System (TEWLS) Tri-Service)	0.000	0.000	-	-	-
Description: Theater Enterprise-Wide Logistics System (TEWLS) supports critical medical logistics warfighter requirements in a net-centric environment. It ties the national, regional, and deployed units into a single business environment. It creates the necessary links for planners, commercial partners, and AMEDD logisticians to accomplish essential care in the theater through a single customer facing portal. It removes disparate data and replaces it with a single instance of actionable data. TEWLS supports today´s modern, non-contiguous battlefield at the regional, COCOM, and Service levels by leveraging emerging Medical Materiel Executive Agency and Theater Lead Agent infrastructure concepts to manage the entire medical supply chain from the industrial base to the end user. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	-	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 481A / *Theather Enterprise Wide Logistics System (TEWLS) Tri-Service)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 482A / *E-Commerce (DHA)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
482A: *E-Commerce (DHA)*	7.803	2.665	2.829	3.704	-	3.704	4.200	4.284	4.370	4.457	Continuing	Continuing

A. Mission Description and Budget Item Justification

The DHP, RDT&E appropriation includes the following TMA initiatives: Electronic Commerce System(E-Commerce): This system was developed for centralized collection, integration, and reporting of accurate purchased care contracting and financial data. It provides an integrated set of data reports from multiple data sources to management, as well as tools to control the end-to-end program change management process. E-Commerce replaces multiple legacy systems. E-Commerce consists of several major subsystems including: CM subsystem utilizing Prism software to support contract action development and documentation; the RM subsystem utilizing Oracle Federal Financials and TED interface software to support the budgeting, accounting, case recoupment, and disbursement processes; the document management subsystem utilizing Documentum software to provide electronic storage, management, and retrieval of contract files; Management Tracking and Reporting subsystem utilizing custom software to provide reports to assist in the management and tracking of changes to the managed care contracts as well as current and out year liabilities; the Purchased Care Web site that provides up-to-date financial information for both TMA and the Services concerning the military treatment facilities' (MTFs') expenditures for MTF enrollee purchased care and supplemental care. E-Commerce includes 5 major subsystems and over 60 servers supporting development, test, and production. The system will be utilized by several hundred users in more than 7 different organizations. Project oversight and coordination must be provided to ensure that the needs of the disparate organizations are met without impacting the system performance or support to any individual user. Server configurations must be kept current in terms of security policies, user authorizations, and interactions with other systems and functions. All of these activities must be managed and coordinated on a daily basis.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: E-Commerce (DHA)	2.665	2.829	3.704	-	3.704
Description: The DHP, RDT&E appropriation includes the following TMA initiatives: Electronic Commerce System(E-Commerce): This system was developed for centralized collection, integration, and reporting of accurate purchased care contracting and financial data. It provides an integrated set of data reports from multiple data sources to management, as well as tools to control the end-to-end program change management process. E-Commerce replaces multiple legacy systems. E-Commerce consists of several major subsystems including: CM subsystem utilizing Prism software to support contract action development and documentation; the RM subsystem utilizing Oracle Federal Financials and TED interface software to support the budgeting, accounting, case recoupment, and disbursement processes; the document management subsystem utilizing Documentum software to provide electronic storage, management, and retrieval of contract files; Management Tracking and Reporting subsystem utilizing custom software to provide reports to assist in the management and tracking of changes to the managed care contracts as well as current and out year liabilities; the Purchased Care Web site that provides up-to-date financial information for both TMA and the Services concerning the military treatment facilities' (MTFs') expenditures for MTF enrollee purchased care and supplemental care. E-					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 482A / *E-Commerce (DHA)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Commerce includes 5 major subsystems and over 60 servers supporting development, test, and production. The system will be utilized by several hundred users in more than 7 different organizations. Project oversight and coordination must be provided to ensure that the needs of the disparate organizations are met without impacting the system performance or support to any individual user. Server configurations must be kept current in terms of security policies, user authorizations, and interactions with other systems and functions. All of these activities must be managed and coordinated on a daily basis. ***FY 2016 Accomplishments:*** FY16 accomplishments pared down initiatives for centralized collection, integration, and reporting of accurate purchased care contracting and financial data. ***FY 2017 Plans:*** FY17 plans include compliance enhancements and modernization of healthcare financial processing, contract operations, and financial reporting. In addition, improve application functionality to respond to changes in healthcare policy and guidance, to improve operational efficiency, and to continue providing DHA operational personnel with effective financial, contract management, and acquisition management capabilities, improve healthcare claims and financial processing to accommodate new healthcare contracts, to support processing changes in healthcare requirements, and to improve private sector care contractor performance assessment and deliverable processing, and enhance accounting and finance capabilities to improve the tracking of pharmaceutical manufacturer refunds, dispute handling, collections, and case management. Plans also include improvements to support healthcare accounting operations, financial audit support, financial reporting, and private sector care budget management and the implementation of software changes, mandated by Congress and the DoD, to accommodate financial application healthcare policy modifications, BEA SFIS changes, and PDS compliance. ***FY 2018 Base Plans:*** In FY18, plans include more modernization to healthcare financial processing, contracts, and reporting as well as adapting to health care policy and guidance. This funding will help to improve operational efficiency for DHA personnel in areas of new health care contracts, processing changes to requirements, and improving private sector care assessments and deliverable processing. Other plans include accounting improvements and better budget management. There will also be software changes, mandated by Congress and the DoD to accommodate financial application policy modifications, BEA SFIS changes, and PDS compliance.					
Accomplishments/Planned Programs Subtotals	2.665	2.829	3.704	-	3.704

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 482A / *E-Commerce (DHA)*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807752HP: *Miscellaneous Support Activities*	14.615	14.933	14.438	-	14.438	14.286	14.543	-	-	Continuing	Continuing
• BA-3, 0807721HP: *Replacement/Modernization*	0.000	0.000	0.000	-	0.000	0.549	0.560	-	-	Continuing	Continuing

Remarks

Program transfer from project 480R.

D. Acquisition Strategy

N/A

E. Performance Metrics

The benchmark performance metric for transition of research supported in this PE will be the attainment of a maturity level that is typical of TRL8.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 490I / *Navy Medicine Chief Information Officer*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
490I: *Navy Medicine Chief Information Officer*	6.237	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Navy Medicine CIO Management Operations - IM/IT RDT&E requests will be vetted through the Bureau of Navy Medicine (BUMED) Governance Process. BUMED IM/IT CIO Governance will monitor progress and milestones every six months.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Navy Medicine Chief Information Officer (CIO) Management Operations	0.000	0.000	-	-	-
Description: Navy Medicine CIO Management Operations - IM/IT RDT&E requests will be vetted through the Bureau of Navy Medicine (BUMED) Governance Process. BUMED IM/IT CIO Governance will monitor progress and milestones every six months. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	-	-	-

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	82.274	82.427	83.778	-	83.778	68.129	71.102	72.458	-	Continuing	Continuing
• BA-1, PE 0807795HP: *Base Communications - CONUS*	16.835	17.153	17.458	-	17.458	17.793	18.151	18.505	-	Continuing	Continuing
• BA-1, PE 0807995HP: *Base Communications - OCONUS*	2.505	2.552	2.599	-	2.599	2.646	2.696	2.750	-	Continuing	Continuing
• BA-3, PE 0807721HP: *Replacement/Modernization*	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 490I / *Navy Medicine Chief Information Officer*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 490J / *Navy Medicine Online*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
490J: *Navy Medicine Online*	3.369	1.890	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Navy Medicine Online System (NMO) is the designated data broker for Navy Medicine. Previous to FY 2016 Navy used funding to provide support on various initiatives. Funding transferred to Defense Health Agency starting in FY 2016. FY 2016 funding will be used for application platform usability and interoperability to deliver apps for patients and staff.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Navy Medicine Online (NMO)	1.890	0.000	0.000	0.000	0.000
Description: The Navy Medicine Online System (NMO) is the designated data broker for Navy Medicine. Funding transferred to Defense Health Agency starting in FY 2016. ***FY 2016 Accomplishments:*** Funding transferred from Navy Medical Information Technology to Defense Health Agency Health Information Technololgy in FY 2016. RDT&E funds used for application platform usability and interoperability to deliver apps for patients and staff. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Base Plans:*** No Funding Programmed. ***FY 2018 OCO Plans:*** No Funding Programmed.					
Accomplishments/Planned Programs Subtotals	1.890	0.000	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 490J / *Navy Medicine Online*

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480A / *Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480A: *Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) (Tri-Service)*	0.000	2.350	1.791	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

ESSENCE is the global, MHS monitoring capability for the early detection of health threats to force readiness. The Armed Forces Health Surveillance Center (AFHSC), the Service-specific public health centers, and Medical Treatment Facilities (MTFs) worldwide use ESSENCE on a daily basis to monitor the health status of the Military Health System (MHS) population in a time of concerns about possible biomedical terrorist attack and naturally occurring emerging infections. ESSENCE monitors the direct care MHS population, containing data on over 9 million lives. ESSENCE facilitates recognition and investigation of Tri-Service Reportable Medical Events and permits access to aggregate data and individual data to analyze the epidemiologic characteristics of health events of interest for Medical situational awareness.

This initiative is a split investment from the original Executive Information/Decision Support (EI/DS) initiative for reporting purposes.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE)	2.350	1.791	0.000	-	0.000
Description: Web-based syndromic surveillance used worldwide to identify rapid or unusual increases in certain syndromes. Automatically alerts users to these unusual increases and uses geographic information system mapping to display occurrences geographically. ***FY 2016 Accomplishments:*** FY16 accomplishments include the continued development of Enhanced Query capabilities which will substantially expand the scope of the current query functionality. The enhanced query functionality will allow user to include parameters from all current and future data sources to create specific disease case definitions. The query will also enable the user to define a specific population, e.g., one or more MTFs, age-groups, etc. This enhanced functionality will expand ESSENCE's scope beyond the existing broad syndromes and allow users to monitor specific diseases, e.g., influenza. ***FY 2017 Plans:*** FY17 plans include the final development and deployment of the Enhanced Query capability and test the Enhanced Data Storage which will expand the data storage capability from 18 months to 5 years. The expansion					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480A / *Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) (Tri-Service)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
of data available will improve the near real time health surveillance, allowing comparisons between the same season and other defined periods of time across multiple years. Without comparison data, unnecessary investigations from false alarms and can result. In addition, plans are to deploy a GIS Capability enabling advanced geospatial analysis. This will restore functionality that does not work properly following application of a STIG during the development of ESSENCE Block III. The GIS capability will allow ESSENCE users to build queries that identify and locate zip codes and MTFs and highlight, zoom to, and center on the results of queries. ***FY 2018 Base Plans:*** No funding programmed.					
Accomplishments/Planned Programs Subtotals	2.350	1.791	0.000	-	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1: *0807793DHA: MHS Tri-Service Information*	5.147	6.459	6.609	0.000	6.609	6.729	6.863	7.000	7.140	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 480Z / *Patient Assessment Screening Tool Outcome Registry (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480Z: *Patient Assessment Screening Tool Outcome Registry (Tri-Service)*	0.000	0.000	0.828	0.538	-	0.538	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

PASTOR is a GOTS system based recommendations from the Pain Management Taskforce (PMTF) to adopt a clinical information system that provides standardized pain assessment with an outcome registry to promote consistency in pain care delivery, and from National Institute of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS) to deliver computerized adaptive testing through various information communication modalities and provide decision support for patients and clinical staffs.

When deployed, PASTOR will support tracking/reporting of Warrior Transition Care, prescription opioid analgesics usage, poly-pharmacy, and sole prescriber program. PASTOR will also be used to evaluate performance/impact of Pain Departments, Interdisciplinary Pain Management Centers, and pain management programs in Patient Centered Medical Home. It will provide clinicians and MHS decision makers with data related to the appropriateness and effectiveness of a spectrum of Pain Management procedures and techniques. It will also provide a capability to meet emerging Joint Commission requirements for measuring and reporting patient reported outcomes. This initiative will enable more consistent pain treatment; greater accuracy in modeling requirements for pain medicine, personnel, equipment and space, specialty care referrals; and greater fidelity on impact of pain on Traumatic Brian Injury (TBI) and co-morbid behavioral health conditions.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Patient Assessment Screening Tool Outcome Registry (PASTOR) (Tri-Service)	0.000	0.828	0.538	-	0.538
Description: Current capabilities completed with advanced concept technology re-modernization funding, reported under the MHS Information Technology Research Projects (MHSITRP) initiative, at pilot facilities include: • Capability to create, store, deliver, and maintain patient reported responses to outcome measurement questions. • Capability for patient to complete questionnaire with computer adaptive testing on self-entered electronic data device either through the internet, via a patient portal or in the clinic setting. • Capability for staff to view the patient self- entered data (ie. dashboard, visual representation, trends reports, and summaries). • Capability to provide decision support for staff based on data collected from patient (i.e. identify risk or potential problems, summarizing key information, follow trends over time, medication order sets, evaluate effectiveness of interventions).					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480Z / *Patient Assessment Screening Tool Outcome Registry (Tri-Service)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
• Capability to identify and enroll patients in a pain management registry (which is a part of the PASTOR package and maintained at Madigan). ***FY 2016 Accomplishments:*** No funding programmed. ***FY 2017 Plans:*** FY17 plans include the development/integration to provide pain patient focused outcomes data to improve clinical decision making, develop data driven and military specific clinical practice guidelines, obtain critical data to assure needs based alignment of resources, and integrate existing validated outcome measures into PASTOR (data is collected and is waiting on analysis). ***FY 2018 Base Plans:*** FY18 plans include the continuation of the building and integration to provide pain patient focused outcomes data to improve clinical decision making, develop data driven and military specific clinical practice guidelines, obtain critical data to assure needs based alignment of resources, and integrate existing validated outcome measures into PASTOR (data is collected and is waiting on analysis). In addition, the plan is to complete enterprise deployment of PASTOR to Pain Departments, Interdisciplinary Pain Management Centers, and in support of pain management care in Patient Centered Medical Homes in the MHS and to continue sustainment and maintenance of all deployed sites.					
Accomplishments/Planned Programs Subtotals	0.000	0.828	0.538	-	0.538

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1: *0807793DHA: MHS Tri-Service Information*	0.000	1.138	1.221	0.000	1.221	0.000	0.000	0.000	0.000	Continuing	Continuing
• BA-3: *0807721DHA: Other Procurement, Replacement/Modernization*	0.000	0.864	0.065	0.000	0.065	0.000	0.000	0.000	0.000	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480Z / *Patient Assessment Screening Tool Outcome Registry (Tri-Service)*

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 480R / *Joint Disability Evaluation System IT (DHA)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
480R: *Joint Disability Evaluation System IT (DHA)*	0.000	0.000	0.445	0.588	-	0.588	0.666	0.679	0.692	0.706	Continuing	Continuing

A. Mission Description and Budget Item Justification

JDES-IT will provide case level management, tracking and reporting capability that will provide Disability Evaluation System (DES) processors and stakeholders increased transparency of a case through an automated IT solution. Case files and DES information will be electronically transferred and shared within Service components, between the Services, and with Veterans Affairs. The future environment would also include information exchange capability with existing Human Resources (HR) and medical systems to reduce duplicative entry. Funding previously reported under Disability Mediation Service prior to finalize decision on the JDES-IT.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Title: Joint Disability Evaluation System IT (JDES-IT)	0.000	0.445	0.588	-	0.588
Description: JDES-IT will provide case level management, tracking and reporting capability that will provide Disability Evaluation System (DES) processors and stakeholders increased transparency of a case through an automated IT solution. ***FY 2016 Accomplishments:*** Funding not programmed for this project in FY 2016. ***FY 2017 Plans:*** In FY17, plans include the identification and documentation of "As Is" and "To Be" business workflows, analysis of JDES-IT requirements support the "To Be" business workflows, finalization of JDES-IT functional requirements, and identification of JDES-IT technical requirements and solution alternatives. ***FY 2018 Base Plans:*** In FY18 plans include funding the below requirements intended to reduce technology risks associated with the JDES-IT product solution and to develop a sufficient understanding of a solution baseline to make sound business decisions on initiating a formal acquisition: 1. Review and validate final capability requirements. 2. Review and validate final system requirements. 3. Complete preliminary product design and reviews. 4. Start critical design.					

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 480R / *Joint Disability Evaluation System IT (DHA)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
5. Review test readiness requirements.					
Accomplishments/Planned Programs Subtotals	0.000	0.445	0.588	-	0.588

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605023DHA *I Integrated Electronic Health Record (iEHR)*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	48.426	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
444A: *Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)*	41.148	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
444B: *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)*	4.720	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
449A: *Virtual Lifetime Electronic Record (VLER) HEALTH*	2.558	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
Program MDAP/MAIS Code: **Project MDAP/MAIS Code(s):** 465												

A. Mission Description and Budget Item Justification

In March 2008, the MHS embarked upon Electronic Health Record (EHR) modernization planning, establishing the initial Electronic Health Records Way Ahead (EHRWA).

In March 2011, the Program was expanded to include the VA in a joint initiative to implement a new, integrated electronic health record for both Departments, called the Integrated Electronic Health Record (iEHR) program.

Secretary Hagel's Memorandum titled "Integrated Electronic Health Records," dated May 2013, provided additional direction to the program:

• DoD shall continue near-term coordinated efforts with VA to develop data federation, presentation, and interoperability. This near-term goal shall be pursued as a first priority separately from the longer-term goal of health record information technology (IT) modernization.

• DoD shall pursue a full and open competition for a core set of capabilities for EHR modernization.

To fulfill Secretary Hagel's directive, parallel programs have been defined, splitting the original iEHR program into two distinct areas. In the Under Secretary of Defense for Acquisition, Technology and Logistics (USD (AT&L)) Acquisition Decision Memoranda (ADM), dated June 21, 2013 and January 2, 2014, the former joint DoD and VA Integrated Electronic Health Record (iEHR) program was restructured to pursue two separate but related healthcare information technology efforts, the DoD Healthcare Management System Modernization (DHMSM) program and a newly defined iEHR focused on providing seamless integrated sharing of electronic health

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605023DHA *I Integrated Electronic Health Record (iEHR)*

data between the DoD and VA to be called Defense Medical Information Exchange (DMIX). The remaining iEHR Increment 1 (iEHR Inc 1) was significantly de-scoped to only the Medical Single Sign-on/Context management (MSSO/CM) implemented at James A. Lovell Federal Health Care Center (JAL FHCC).

iEHR RDT&E is reported under the program element (PE) 0605013 through FY 2013 inclusive, but iEHR, VLER Health and DHMSM will be reported under new program element 0605023 for FY 2014.

In FY 2015, PE 0605023 will report only iEHR and VLER Health since DHMSM will have its own PE starting in FY 2015.

In FY 2016 and out, only iEHR Increment 1 will be reported in PE 0605023. DHMSM will continue to be only initiative reported in PE 0605026. However, new PE 06050039 is established for DMIX for FY 2016 and out. DMIX will incorporate the previous VLER Health and JEHRI initiatives.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	9.216	0.000	0.000	-	0.000
Current President's Budget	0.000	0.000	0.000	-	0.000
Total Adjustments	-9.216	0.000	0.000	-	0.000
• Congressional General Reductions	-8.968	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.248	-			

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605023-Integrated Electronic Health Record (iEHR) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program.

FY 2017: No change

FY 2018: No change

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605023DHA / *Integrated Electronic Health Record (iEHR)*	**Project (Number/Name)** 444A / *Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
444A: *Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)*	41.148	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Project MDAP/MAIS Code: 465

A. Mission Description and Budget Item Justification

In March 2008, the MHS embarked upon Electronic Health Record (EHR) modernization planning, establishing the initial Electronic Health Records Way Ahead (EHRWA).

In March 2011, the Program was expanded to include the VA in a joint initiative to implement a new, integrated electronic health record for both Departments, called the Integrated Electronic Health Record (iEHR) program.

Secretary Hagel's Memorandum titled "Integrated Electronic Health Records," dated May 2013, provided additional direction to the program:

• DoD shall continue near-term coordinated efforts with VA to develop data federation, presentation, and interoperability. This near-term goal shall be pursued as a first priority separately from the longer-term goal of health record information technology (IT) modernization.

• DoD shall pursue a full and open competition for a core set of capabilities for EHR modernization.

To fulfill Secretary Hagel's directive, parallel programs have been defined, splitting the original iEHR program into two distinct areas. In the Under Secretary of Defense for Acquisition, Technology and Logistics (USD (AT&L)) Acquisition Decision Memoranda (ADM), dated June 21, 2013 and January 2, 2014, the former joint DoD and VA Integrated Electronic Health Record (iEHR) program was restructured to pursue two separate but related healthcare information technology efforts, the DoD Healthcare Management System Modernization (DHMSM) program and a newly defined iEHR focused on providing seamless integrated sharing of electronic health data between the DoD and VA to be called Defense Medical Information Exchange (DMIX). The remaining iEHR Increment 1 (iEHR Inc 1) was significantly de-scoped to only the Medical Single Sign-on/Context management (MSSO/CM) implemented at James A. Lovell Federal Health Care Center (JAL FHCC).

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX) (Tri-Service)	0.000	-	-
Description: The iEHR Increment 1 initiative achieved Full Deployment Decision November 2014 and is targeted to reach Full Deployment milestone by May 2016. Sustainment efforts for iEHR Increment 1 include the DoD sustainment of the James A			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605023DHA / *Integrated Electronic Health Record (iEHR)*	**Project (Number/Name)** 444A / *Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Lovell Federal Health Care Center (JAL FHCC) health care information technology that includes medical single sign-on/context management (MSSO/CM). Program funding is also included to maintain DoD operations at the Interagency Program Office (IPO). • The DoD/VA Interagency Program Office (IPO) was re-chartered on December 5, 2013. The mission focus is addressing and coordinating the establishment of a clinical and technical standards profile and processes for data interoperability to create seamless integration of health data for DoD and VA. The IPO will leverage national and international standards and open architecture design principles to preserve flexibility, and foster data interoperability with each other and appropriate commercial entities. The IPO will enhance existing DoD and VA efforts with The Office of the National Coordinator (ONC) for Health Information Technology within the Health and Human Services (HHS) and other national and international standards organizations and coordinate and monitor the common components required for health data sharing and interoperability. The primary deliverables include technical data interoperability architecture requirements, interface control documentation, terminology standards identification and data exchange guidance. ***FY 2016 Accomplishments:*** SBIR			
Accomplishments/Planned Programs Subtotals	0.000	-	-

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, PE 0807784DHA: *Information Technology Development* -	17.176	17.183	16.284	-	16.284	16.505	17.958	16.883	17.222	Continuing	Continuing
• BA-3, 0807784DHA: *Replacement/Modernization*	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605023DHA / *Integrated Electronic Health Record (iEHR)*	**Project (Number/Name)** 444B / *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
444B: *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)*	4.720	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

DHMSM will acquire and support deployment, and implementation of an electronic health record (EHR) system that replaces the DoD legacy MHS inpatient and outpatient EHR systems. Overarching goal of the program is to enable healthcare teams to deliver high-quality, safe care and preventive services to patients through the use of easily accessible standards-based computerized patient records resulting in: improved accuracy of diagnoses and medication; improved impact on health outcomes; increased patient participation in the healthcare process; improved patient-centered care coordination; and increased practice efficiencies in all settings, including operational environments.

DHMSM replaces DoD legacy healthcare systems with a commercial solution in use in other medical systems that is open, rendered as a modular architecture, using standards-based/non-proprietary interfaces. DHMSM will support the Department's goals of net centricity by providing a framework for full human and technical connectivity and interoperability that allows DoD users and mission partners to share the information they need, when they need it, in a form they can understand and act on with confidence, and protects information from those who should not have it. Once fielded, the EHR will support the following healthcare activities for DoD's 44,000 practitioners and 9.5 million beneficiaries.

1. Clinical workflow and provider clinical decision support;
2. Capture, maintain, use, protect, preserve and share health data and information;
3. Retrieval and presentation of health data and information that is meaningful for EHR users regardless of where the patient's records are physically maintained; and
4. Analysis and management of health information from multiple perspectives to include population health, military medical readiness, clinical quality, disease management, and medical research.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: DoD Healthcare Management System Modernization (DHMSM)	0.000	0.000	-
Description: DHMSM will be executed to deliver uniform information management options across both garrison and theater environments. DHMSM will focus on replacement of inpatient and outpatient systems, and will encompass deployment of the enterprise EHR to fixed facilities as well as expeditionary components.			
FY 2016 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605023DHA / *Integrated Electronic Health Record (iEHR)*	**Project (Number/Name)** 444B / *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605023DHA / *Integrated Electronic Health Record (iEHR)*	Project (Number/Name) 449A / *Virtual Lifetime Electronic Record (VLER) HEALTH*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
449A: *Virtual Lifetime Electronic Record (VLER) HEALTH*	2.558	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The primary goal of the VLER Health initiative is to enable the secure sharing of health information (i.e., demographic and clinical data) between DoD and external Federal and private sector partners which meets Meaningful Use (MU) requirements to improve healthcare quality, safety, and efficiency. By electronically sharing health information using national standards, that information can support tracking key clinical conditions, communicating that information to better coordinate care, and engaging patients in their own care. The VLER Health initiative provides clinicians with the most up-to-date information, potentially reducing redundant diagnostic tests, medical errors, paperwork and handling, and overall healthcare costs. These benefits, in turn, align with the MHS quadruple aim by ensuring that the military force is medically ready to deploy; the military beneficiary population remains healthy through focused prevention; patient care is convenient, equitable, safe, and of the highest quality; and the total cost of healthcare is reduced through the reduction of waste and focus on quality

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Virtual Lifetime Electronic Record (VLER) HEALTH	0.000	0.000	-
Description: Pursue the primary goal of the VLER Health initiative is to enable the secure sharing of health information (i.e., demographic and clinical data) between DoD and external Federal and private sector partners which meets Meaningful Use (MU) requirements to improve healthcare quality, safety, and efficiency. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, PE 0807784: *Integrated Electronic Health Record (iEHR)*	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	Continuing	Continuing
• BA-3, PE 0807784: *Replacement/ Modernization, Integrated Electronic Health Record*	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605023DHA / *Integrated Electronic Health Record (iEHR)*	**Project (Number/Name)** 449A / *Virtual Lifetime Electronic Record (VLER) HEALTH*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605025DHA *I Theater Medical Information Program - Joint (TMIP-J)*

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
Total Program Element	45.186	21.338	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
445A: *Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)*	45.186	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
445B: *Operational Medicine Support*	0.000	21.338	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Program MDAP/MAIS Code:
Project MDAP/MAIS Code(s): M07

A. Mission Description and Budget Item Justification

TMIP-J is a suite of system applications that is currently deployed to all Services as the primary healthcare information technology (IT) system supporting the Warfighter. TMIP-J integrates components of the Service's sustaining base systems and the medical information systems to ensure timely interoperable medical support for mobilization, deployment and sustainment of Theater and deployed forces. TMIP-J enhances the clinical care and information capture at all levels of care in Theater, transmits critical information to the Theater Commander, the evacuation chain for combat and non-combat casualties, and provides input to a service member's longitudinal health record. TMIP-J provides information at the point of injury and to the Theater tactical and strategic decision makers through data capture and transmission to a single Theater Management Data Store (TMDS). Using TMDS, TMIP-J provides the integration with external systems for medical logistics, patient movement and tracking, and medical command and control and medical situational awareness. TMIP-J system components integrate to specific tactical requirements, providing for availability in no- and low- communications environment through store and forward capture and transmission technology. The Theater Medical Information Program - Joint (TMIP-J) is in sustainment; Full Deployment declared May 2016.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	22.100	0.000	0.000	-	0.000
Current President's Budget	21.338	0.000	0.000	-	0.000
Total Adjustments	-0.762	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.762	-			

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605025DHA *I Theater Medical Information Program - Joint (TMIP-J)*

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605025-Theater Medical Information Program - Joint (TMIP-J) (-$0.762 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$0.762 million).

FY 2017: No change

FY 2018: No change.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605025DHA / *Theater Medical Information Program - Joint (TMIP-J)*	**Project (Number/Name)** 445A / *Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
445A: *Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)*	45.186	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Project MDAP/MAIS Code: M07

A. Mission Description and Budget Item Justification

TMIP-J is a suite of system applications that is currently deployed to all Services as the primary healthcare information technology (IT) system supporting the Warfighter. TMIP-J integrates components of the Service's sustaining base systems and the medical information systems to ensure timely interoperable medical support for mobilization, deployment and sustainment of Theater and deployed forces. TMIP-J enhances the clinical care and information capture at all levels of care in Theater, transmits critical information to the Theater Commander, the evacuation chain for combat and non-combat casualties, and provides input to a service member's longitudinal health record. TMIP-J provides information at the point of injury and to the Theater tactical and strategic decision makers through data capture and transmission to a single Theater Management Data Store (TMDS). Using TMDS, TMIP-J provides the integration with external systems for medical logistics, patient movement and tracking, and medical command and control and medical situational awareness. TMIP-J system components integrate to specific tactical requirements, providing for availability in no- and low- communications environment through store and forward capture and transmission technology. The Theater Medical Information Program - Joint (TMIP-J) is in sustainment; Full Deployment declared May 2016.

TMIP-J RDT&E is reported under the program element 0605013 through FY 2013 inclusive, but will be reported under new program element 0605023 for FY 2014 and out.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)	0.000	0.000	0.000
Description: The Theater Medical Information Program - Joint (TMIP-J) is in sustainment; Full Deployment declared May 2016. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605025DHA / *Theater Medical Information Program - Joint (TMIP-J)*	**Project (Number/Name)** 445A / *Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	62.170	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
• BA-1, 0807744DHA: *Theater Medical Information Program - Joint (TMIP-J)*	0.000	49.857	57.326	-	57.326	36.947	32.107	27.049	27.592	Continuing	Continuing
• BA-3, 0807744DHA: *Theater Medical Information Program - Joint (TMIP-J)*	1.494	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources. Performance metrics for specific projects may be viewed at the OMB Federal IT Dashboard website.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605025DHA / *Theater Medical Information Program - Joint (TMIP-J)*	Project (Number/Name) 445B / *Operational Medicine Support*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
445B: *Operational Medicine Support*	0.000	21.338	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Support Joint Operational Medicine Information System (JOMIS).

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Operational Medicine Support	21.338	0.000	0.000
Description: Support Joint Operational Medicine Information System (JOMIS). ***FY 2016 Accomplishments:*** Funding will be used for Joint Operational Medicine Information System (JOMIS). • Completed the DHMSM EHR (MHS Genesis) Product Evaluation in support of JOMIS Increment 1 • Stand-up of the Operational Medicine Government Approved Lab Testing Facility • Initiate Test Risk Reduction and Integration activities using the MHS Genesis Product at the Testing Facility • Support for the Theater Medical Information Requirements Capability Development Document (TMIR-CDD) • Continue business management operations • Operate and maintain Operational Medicine Government Approved Lab Testing Facility JOMIS will be reported under PE 0605045DHA in FY17 and out per Departmental direction for increased transparency. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	21.338	0.000	0.000

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605025DHA / *Theater Medical Information Program - Joint (TMIP-J)*	**Project (Number/Name)** 445B / *Operational Medicine Support*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-3, 0807744DHA: *Theater Medical Information Program - Joint*	1.494	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
• BA-1, 0807744DHA **: *Theater Medical Information Program - Joint*	0.000	49.857	57.326	0.000	57.326	36.947	32.107	27.049	27.592	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605026DHA *I Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)*

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
Total Program Element	88.744	362.788	298.623	42.549	-	42.549	10.326	10.071	10.743	10.478	Continuing	Continuing
483A: *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA*	88.744	362.788	298.623	42.549	-	42.549	10.326	10.071	10.743	10.478	Continuing	Continuing

Program MDAP/MAIS Code:
Project MDAP/MAIS Code(s): 496

A. Mission Description and Budget Item Justification

DHMSM will replace the DoD legacy healthcare management systems with a commercial off-the-shelf capability that is open, modular, and standards-based with non-proprietary interfaces. DHMSM will support the Department's goals of net- centricity by providing a framework for full human and technical connectivity and interoperability that allows DoD users and mission partners to share the information they need, when they need it, in a form they can understand and act on with confidence, and protects information from those who should not have it. Once fielded, the EHR will support the following healthcare activities for DoD's practitioners and beneficiaries:

- Clinical workflow and provider clinical decision support;
- Capture, maintain, use, protect, preserve and share health data and information;
- Retrieval and presentation of health data and information that is meaningful for EHR users regardless of where the patient's records are physically maintained; and
- Analysis and management of health information from multiple perspectives to include population health, military medical readiness, clinical quality, disease management, and medical research.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	438.376	298.623	42.549	-	42.549
Current President's Budget	362.788	298.623	42.549	-	42.549
Total Adjustments	-75.588	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-42.005	-			
• SBIR/STTR Transfer	-33.583	-			

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605026DHA *I Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)*

Change Summary Explanation

FY 2016: Prior approval reprogramming from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605026-Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) (-$42.005 million) to DHP RDT&E, PE Joint Operational Medicine Information System (JOMIS) (+$42.005 million).

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605026 DoD Healthcare Management System Modernization (DHMSM) (-$33.583 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$33.583 million).

FY 2017: No change

FY 2018: No change

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605026DHA / *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)*	**Project (Number/Name)** 483A / *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
483A: *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA*	88.744	362.788	298.623	42.549	-	42.549	10.326	10.071	10.743	10.478	Continuing	Continuing

Project MDAP/MAIS Code: 496

A. Mission Description and Budget Item Justification

DHMSM will replace the DoD legacy healthcare management systems with a commercial off-the-shelf capability that is open, modular, and standards-based with non-proprietary interfaces. DHMSM will support the Department's goals of net- centricity by providing a framework for full human and technical connectivity and interoperability that allows DoD users and mission partners to share the information they need, when they need it, in a form they can understand and act on with confidence, and protects information from those who should not have it. Once fielded, the EHR will support the following healthcare activities for DoD's practitioners and beneficiaries: (1) clinical workflow and provider clinical decision support; (2) capture, maintain, use, protect, preserve and share health data and information; (3) retrieval and presentation of health data and information that is meaningful for EHR users regardless of where the patient's records are physically maintained; and (4) analysis and management of health information from multiple perspectives to include population health, military medical readiness, clinical quality, disease management, and medical research.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: DoD Healthcare Management System Modernization (DHMSM) Program	362.788	298.623	42.549
Description: The DHMSM program acquired an integrated inpatient/outpatient Best of Suite (BoS) electronic health record (EHR) solution, augmented by the Best of Breed (BoB) product(s). The overarching goal of the program is to enable healthcare teams to deliver high-quality, safe, care and preventive services to patients through the use of easily accessible standards-based computerized patient records. The anticipated benefits include: improved accuracy of diagnoses and medication; improved impact on health outcomes; increased patient participation in the healthcare process; improved patient-centered care coordination; and increased practice efficiencies in all settings, including all DoD operational environments.			
FY 2016 Accomplishments: FY16 Accomplishments include the development of the Detailed Government Test Plan, Reviewed vendor Test Cases, conducting 12 Test Integration Work Groups (TIWG) to work with external Test Agencies and Stakeholders on test planning efforts. In addition, this program started contractor led Configuration and Integration Testing (CIT) of EHR system, completed the development of Implementation Plan which will be utilized for Go-Live of the EHR at the Initial Operational Capability (IOC)			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605026DHA / *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)*	**Project (Number/Name)** 483A / *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
locations in the Pacific Northwest, managed selection of medical and peripheral devices for test, observed the installation, and testing of medical and peripheral devices in the Fixed Facility Government Approved Labs (GAL). • Prepared analyses and documentation for and conducted multiple Integrated Baseline Reviews for the program. • Conducted multiple engineering and readiness reviews, continued business management operations, and contract management oversight. ***FY 2017 Plans:*** In FY17, continued plans include the support the continued software configuration, integration, and testing of multiple interfaces with the modernized EHR. This includes direct coordination with Interface Partners for interface control document development and test execution support. In addition, plans are to conduct System Engineering Technical Review 3 (SETR) Final Design Review (FDR) in support of scheduled Limited Fielding for IOC Authority to Proceed, the Segment 1 Test Readiness, conduct Operational Test Readiness review and execute Operational Assessment and Operational Test of Segment 1, support the long lead procurement efforts for the Go-Live of multiple Military Treatment Facilities (MTFs) post Full Deployment Decision in accordance with the Milestone Decision Authority approved schedule. Other plans include the operation and maintenance of the DHMSM system, including recurring configuration, integration, and test activities, software license maintenance, hardware refresh, system hosting, and recurring change management and training as applicable and continued business management operations and contract management oversight. ***FY 2018 Plans:*** For FY18, plans include the continued support for configuration efforts for interfaces with legacy systems, engineering and configuration at the IOC sites, completing system updates, testing, integration and deployment in response to the results of the Initial Operational Test & Evaluation (IOT&E), and addressing additional configurations identified for the modernized DHMSM EHR during limited fielding for IOC. This will be done by the purchase required commercial software licenses and multiple deployments of the modernized DHMSM EHR to Military Treatment Facilities (MTFs) after the scheduled Full Deployment Decision is approved by the Milestone Decision Authority (MDA); deployment activities include site visits, localized configuration, deployment activities and on-site deployment support for multiple Wave Deployments (each containing multiple MTFs and Clinics), and O&M of the DHMSM system, including recurring configuration, integration, and test activities, software license maintenance, hardware refresh, system hosting, and recurring change management and training as applicable.			
Accomplishments/Planned Programs Subtotals	362.788	298.623	42.549

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605026DHA / *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)*	**Project (Number/Name)** 483A / *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, PE 0807787: *DoD Healthcare Management Systems*	63.130	129.969	203.725	-	203.725	246.122	317.228	340.071	354.515	Continuing	Continuing
• BA-3, PE 0807787: *Information Technology Development and Sustainment - DoD Healthcare Management System Modernization*	0.000	29.468	499.193	-	499.193	547.160	532.476	474.888	266.526	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources are also used.

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Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605039DHA *I PE 0605039HP / DoD Medical Information Exchange and Interoperability*

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
Total Program Element	0.000	10.157	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
458A: *DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)*	0.000	10.157	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

In March 2008, the MHS embarked upon Electronic Health Record (EHR) modernization planning, establishing the initial Electronic Health Records Way Ahead (EHRWA).

In March 2011, the Program was expanded to include the VA in a joint initiative to implement a new, integrated electronic health record for both Departments, called the Integrated Electronic Health Record (iEHR) program.

Secretary Hagel's Memorandum titled "Integrated Electronic Health Records," dated May 2013, provided additional direction to the program:

• DoD shall continue near-term coordinated efforts with VA to develop data federation, presentation, and interoperability. This near-term goal shall be pursued as a first priority separately from the longer-term goal of health record information technology (IT) modernization.

• DoD shall pursue a full and open competition for a core set of capabilities for EHR modernization.

To fulfill Secretary Hagel's directive, parallel programs have been defined, splitting the original iEHR program into two distinct areas. In the Under Secretary of Defense for Acquisition, Technology and Logistics (USD (AT&L)) Acquisition Decision Memoranda (ADM), dated June 21, 2013 and January 2, 2014, the former joint DoD and VA Integrated Electronic Health Record (iEHR) program was restructured to pursue two separate but related healthcare information technology efforts, the DoD Healthcare Management System Modernization (DHMSM) program and a newly defined iEHR focused on providing seamless integrated sharing of electronic health data between the DoD and VA to be called Defense Medical Information Exchange (DMIX). The remaining iEHR Increment 1 (iEHR Inc 1) was significantly de-scoped to only the Medical Single Sign-on/Context management (MSSO/CM) implemented at James A. Lovell Federal Health Care Center (JAL FHCC).

• DMIX established a roadmap outlining the future of health data sharing and viewer capabilities for DoD in support of the guidance provided by the President, Congress, and the Secretary of Defense. The roadmap defined a plan to provide a single viewer to be used by DoD and VA that displays an integrated view of a patient's medical history. The viewer leverages existing inherited DoD data-sharing capabilities, and a VA-provided data service in order to collect the patient's health data from the respective, authoritative data stores. Of the various existing viewers, VA and DoD decided to evolve Joint Legacy Viewer (JLV) as the single viewer for use by both Departments. By adopting JLV as a common viewer between DoD and VA, DMIX met the National Defense Authorization Act FY 2014 (NDAA 2014) requirement for "an integrated display of data" which allows DoD to sunset inherited legacy viewers.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605039DHA *I PE 0605039HP / DoD Medical Information Exchange and Interoperability*

iEHR RDT&E is reported under the program element (PE) 0605013 through FY 2013 inclusive, but iEHR, VLER Health and DHMSM will be reported under new program element 0605023 for FY 2014.

In FY 2015, PE 0605023 will report only iEHR and VLER Health since DHMSM will have its own PE starting in FY 2015.

In FY 2016 and out, only iEHR Increment 1 will be reported in PE 0605023. DHMSM will continue to be only initiative reported in PE 0605026. However, new PE 06050039 is established for DMIX for FY 2016 and out. DMIX will incorporate the previous VLER Health and JEHRI initiatives.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	11.000	0.000	0.000	-	0.000
Current President's Budget	10.157	0.000	0.000	-	0.000
Total Adjustments	-0.843	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.843	-			

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605039-DoD Medical Information Exchange and Interoperability (-$0.843 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$0.843 million).

FY 2017: No change.

FY 2018: No change.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605039DHA / *PE 0605039HP / DoD Medical Information Exchange and Interoperability*	**Project (Number/Name)** 458A / *DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
458A: *DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)*	0.000	10.157	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

DMIX program will acquire the capabilities necessary to securely and reliably exchange standardized, normalized, and correlated health data with all partners through standard data/information exchange mechanisms. This allows users in different places and different organizations to access, use, and supplement health data (technical interoperability) that has a shared meaning so users (assisted by computers) are able to make care decisions (Semantic Interoperability – Level 4). DMIX manages the data exchange capability from legacy data stores in order to prepare for the transition to the modernized Electronic Health Record platform being acquired by DoD Healthcare Management System Modernization (DHMSM). DMIX consists of a family of capability initiatives supporting the seamless exchange of standardized health data among DoD, VA, other Federal agencies, and private providers as well as benefits administrators. The DMIX program provides the capability for health care providers to access and view complete and accurate patient health records from a variety of data sources thereby allowing healthcare providers to make faster and higher quality care decisions. DMIX was established in accordance with the joint memo from USD(C) and USD(AT&L) titled "Joint Memorandum on Major Defense Acquisition Program and Major Automated Information System Program Resource Transparency in Department of Defense Budget Systems" dated June 27, 2013.

In addition, Joint Electronic Health Record Interoperability (JEHRI) and Virtual Lifetime Electronic Record (VLER) Health (to include Exchange) are part of the DMIX program as a direct result of the Acquisition Decision Memorandum (ADM) signed January 2, 2014 by the Under Secretary of Defense for Acquisition, Technology and Logistic (USD AT&L). Use of the health data may be done via legacy systems, clinical mobile applications and system agnostic viewers such as the Joint Legacy Viewer (JLV). Customers include the MHS, VA, other federal agencies and over 200,000 medical care practitioners.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Defense Medical Information Exchange (DMIX) Program	10.157	0.000	0.000
Description: Comprised of the infrastructure and services needed to provide seamless integrated sharing of electronic health data between the DoD, VA, other Federal agencies, and private sector partners that is viewable to DoD and VA providers through a joint viewer.			
FY 2016 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605039DHA / *PE 0605039HP / DoD Medical Information Exchange and Interoperability*	**Project (Number/Name)** 458A / *DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Supported DOT&E Operational Test activities and Joint Interoperability and Test Command (JITC) Certificate of Net-worthiness; continuing in FY 2017 to finish the Adversarial Assessment and Cooperative Vulnerability and Penetration Assessment (CVPA) testing that could not take place in FY 2016 ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	10.157	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA-1, 0807788HP: *DoD Medical Information Exchange and Interoperability*	56.348	56.706	44.743	-	44.743	46.951	47.508	46.794	47.731	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

DMIX is a collaborative effort between the DoD and VA to share Health Care Resources to improve access to, and quality and cost effectiveness of, health care as mandated by law. This investment is deeply embedded in the MHS Enterprise Roadmap as both Departments have need for modernization/ replacement of existing legacy systems. This investment will use a combination of an open architecture approach, and the purchase (in some instances) of GOTS and COTS products.

E. Performance Metrics

Program cost, schedule and performance are measured periodically using a systematic approach as required for Major Automated Information Systems (MAIS) per DoD Directives and Instructions.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605045DHA / *Joint Operational Medicine Information System (JOMIS)*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	0.000	42.005	22.140	87.511	-	87.511	22.619	23.071	23.532	24.003	Continuing	Continuing
447A: *Joint Operational Medicine Information System (JOMIS)*	0.000	42.005	22.140	87.511	-	87.511	22.619	23.071	23.532	24.003	Continuing	Continuing
Program MDAP/MAIS Code: 521												

A. Mission Description and Budget Item Justification

The JOMIS Program will modernize, deploy, and sustain the DoD's operational medicine information systems using MHS GENESIS, while developing and fielding new theater capabilities that enable comprehensive health services to meet Warfighter requirements for military medical operations. JOMIS - MHS GENESIS is intended to function in constrained, intermittent, and non-existent communications environments while providing access to authoritative sources of clinical data. The JOMIS Program is declared Joint Interest for capability requirements to be executed under the Joint Capabilities Integration and Development System (JCIDS), with oversight by the Joint Staff J8 (Force Structure, Resources and Assessments) and the Joint Requirements Oversight Council (JROC).

The JOMIS Increment 1 Program is planned to deliver the MHS GENESIS Electronic Health Record (EHR) to meet the healthcare and dental documentation requirements validated by the JCIDS approved Theater Medical Information Requirements (TMIR) Capabilities Development Document (CDD) signed February 28, 2017. JOMIS Increment 1 is planned to deliver MHS GENESIS to replace/retire the legacy AHLTA-T and TC2 systems (under TMIP-J). The JOMIS Increment 1 Program is pre-Milestone B.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	0.000	22.140	22.180	-	22.180
Current President's Budget	42.005	22.140	87.511	-	87.511
Total Adjustments	42.005	0.000	65.331	-	65.331
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	42.005	-			
• SBIR/STTR Transfer	-	-			
• Departmental Decision	0.000	0.000	65.331	-	65.331

Change Summary Explanation

FY 2016: Reprogramming from DHMSM to JOMIS.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605045DHA *I Joint Operational Medicine Information System (JOMIS)*

FY 2017: No change.

FY 2018: Reprogramming from JOMIS PROC to JOMIS RDT&E.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605045DHA / *Joint Operational Medicine Information System (JOMIS)*	**Project (Number/Name)** 447A / *Joint Operational Medicine Information System (JOMIS)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
447A: *Joint Operational Medicine Information System (JOMIS)*	0.000	42.005	22.140	87.511	-	87.511	22.619	23.071	23.532	24.003	Continuing	Continuing

A. Mission Description and Budget Item Justification

The JOMIS Program will modernize, deploy, and sustain the DoD's operational medicine information systems using MHS GENESIS, while developing and fielding new theater capabilities that enable comprehensive health services to meet Warfighter requirements for military medical operations. JOMIS - MHS GENESIS is intended to function in constrained, intermittent, and non-existent communications environments while providing access to authoritative sources of clinical data. The JOMIS Program is declared Joint Interest for capability requirements to be executed under the Joint Capabilities Integration and Development System (JCIDS), with oversight by the Joint Staff J8 (Force Structure, Resources and Assessments) and the Joint Requirements Oversight Council (JROC).

The JOMIS Increment 1 Program is planned to deliver the MHS GENESIS Electronic Health Record (EHR) to meet the healthcare and dental documentation requirements validated by the JCIDS approved Theater Medical Information Requirements (TMIR) Capabilities Development Document (CDD) signed February 28, 2017. JOMIS Increment 1 is planned to deliver MHS GENESIS to replace/retire the legacy AHLTA-T and TC2 systems (under TMIP-J). The JOMIS Increment 1 Program is pre-Milestone B.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Joint Operational Medicine Information System (JOMIS)	42.005	22.140	87.511
Description: Goals of the JOMIS program include: meet existing and emerging operational medicine requirements in the theater, fully leverage the EHR solution configuration for care in theater, and provide two-way information flow between garrison and theater. Benefits of this program include the delivery of uniform clinical information across both garrison and theater environments through the use of an enterprise-level EHR system, enhancements to the clinical care and information captured at all levels of care in operational environments, transmission of critical information to the combatant commander, the evacuation chain for combat and non-combat casualties, and full interoperability of the theater data with the complete longitudinal health record for delivery to the sustaining base and the Department of Veterans Affairs.			
FY 2016 Accomplishments: In conjunction with funding programmed under Operational Medicine Support Initiative in Program Element 0605025DHA, the start up of JOMIS is pending. So far, accomplishments include: DHMSM EHR (MHS Genesis) Product Evaluation in support of JOMIS Increment 1, the stand-up of the Operational Medicine Government Approved Lab Testing Facility, and the initiation of Test Risk Reduction and Integration activities using the MHS Genesis Product at the Testing Facility.			
FY 2017 Plans:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605045DHA / *Joint Operational Medicine Information System (JOMIS)*	**Project (Number/Name)** 447A / *Joint Operational Medicine Information System (JOMIS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
In continuation with FY16 and in conjunction with the Operational Medicine Support Initiative in PE 0506025DHA, FY17 plans include: establishing Operational Medicine Government Approved Lab (OM GAL) and began early engineering analysis activities for Increment 1, developing draft enterprise architecture products for JOMIS Increment 1, cybersecurity planning for Increment 1, establishing accreditation boundary and RMF requirements; establish Joint Cyber WIPT for JOMIS Increment 1, executing the engagement plan with Services and Combatant Commands for the development of the Training & Deployment Plan and early user adoption analysis activities, developing draft Increment 1 TEMP document, initiating Development Evaluation Framework (DEF), nominating JITC as the Lead Operational Test Agency, and establishing the Joint Testing WIPT with participation from JITC and Service OTAs. Plans also include supporting the development of the Information Systems (IS) Capability Development Document (CDD) for Theater Medical Information Requirements (TMIR). Approval from the Received Joint Requirements Oversight Council (JROC) was received in February 2017. ***FY 2018 Plans:*** In Fy18, plans include continuing the development of acquisition plans & documents to support a “MS B like” event, establishing the cost, performance and schedule baseline for Increment 1. This requires the planning and execution of technology maturation including piloting theater unique capabilities for healthcare delivery; conducting risk reduction activities including systems engineering trade-offs and early analysis activities for the performance of the MHS GENESIS product on tactical hardware and infrastructure in the Operational Medicine Test Lab, Ft Detrick; developing and receiving approval of a Joint Test Management & Evaluation Plan (TEMP) for the execution of development test, operational test and cyber security testing in conjunction with the Services; and initiating Development Test (DT) in Operational Medicine Test Lab, Ft Detrick (dependent of receipt of MHS GENESIS configuration from the DHMSM Program in NLT 2QFY18).			
Accomplishments/Planned Programs Subtotals	42.005	22.140	87.511

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
• BA1 0807746DHA: *JOMIS*	0.200	11.136	13.545	-	13.545	31.549	36.216	42.651	43.415	Continuing	Continuing
• BA3 0807746DHA: *JOMIS*	0.000	2.413	8.326	-	8.326	75.688	75.150	73.605	75.077	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605045DHA / *Joint Operational Medicine Information System (JOMIS)*	**Project (Number/Name)** 447A / *Joint Operational Medicine Information System (JOMIS)*

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources.

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Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605145DHA *I Medical Products and Support Systems Development*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	82.111	15.590	17.954	15.219	-	15.219	20.295	21.589	22.022	22.462	Continuing	Continuing
375A: *GDF-Medical Products and Support System Development*	44.627	13.919	17.180	14.464	-	14.464	19.421	20.654	21.068	21.489	Continuing	Continuing
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	25.334	0.790	0.774	0.755	-	0.755	0.874	0.935	0.954	0.973	Continuing	Continuing
500A: *CSI - Congressional Special Interests*	12.150	0.881	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force – Medical Products and Support Systems Development: This program element (PE) provides funding for system development and demonstration of medical commodities delivered from the various medical advanced development and prototyping Department of Defense (DoD) Components that are directed at meeting validated requirements prior to full-rate initial production and fielding, including initial operational test and evaluation and clinical trials. These clinical trials are conducted to obtain US Food and Drug Administration approval, a requirement for use of all medical products. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of DoD and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP sponsored research. The JPCs supported by this PE include medical simulation and information sciences (JPC-1), military operational medicine (JPC-5) combat casualty care (JPC-6), and clinical and rehabilitative medicine (JPC-8). The funding also supports the clinical evaluation of hyperbaric oxygenation for post-concussion syndrome (PCS). The effort encompasses development, initiation, operation, analysis, and subsequent publication of clinical trials to compare and assess the long-term benefit of hyperbaric oxygen (HBO2) therapy on Service members with PCS. As the research efforts mature, the most promising will transition to production and deployment or to industry.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605145DHA *I Medical Products and Support Systems Development*

The Army Medical Command received DHP Congressional Special Interest (CSI) research funding to Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	15.906	17.954	15.219	-	15.219
Current President's Budget	15.590	17.954	15.219	-	15.219
Total Adjustments	-0.316	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.881	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.197	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 500A: *CSI - Congressional Special Interests*		
Congressional Add: *465A – Program Increase: Restore Core Research Funding Reduction (GDF)*	0.800	-
Congressional Add: *475A – Program Increase: Restore Core Research Funding Reduction (Army)*	0.081	-
Congressional Add Subtotals for Project: 500A	0.881	-
Congressional Add Totals for all Projects	0.881	-

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support Systems Development (-$1.197 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$1.197 million).

FY 2016: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (+$0.881 million).

FY 2017: Realignment from DHP RDTE PE 0605145 (-$0.913 million) to DHP RDTE PE 0603115 for rebalancing JPC portfolios (+$0.913 million).

FY 2017: Realignment from DHP RDTE PE 0605145 (-$0.633 million) to DHP RDTE PE 0603115 for Breast, GYN and Prostate Cancer Centers of Excellence (+ $0.633 million).

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605145DHA *I Medical Products and Support Systems Development*

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605145-Medical Products and Support Systems Development (+$0.594 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+$0.594 million).

FY 2018: No changes.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / *Medical Products and Support Systems Development*	Project (Number/Name) 375A / *GDF-Medical Products and Support System Development*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
375A: *GDF-Medical Products and Support System Development*	44.627	13.919	17.180	14.464	-	14.464	19.421	20.654	21.068	21.489	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Products and Support Systems Development: Activities conducted in this project are intended to support system development and demonstration prior to initial full rate production and fielding of commodities. Medical products and support systems development is managed by the following Joint Program Committees (JPCs). 1- The Medical Simulation and Information Sciences JPC seeks to improve military medical training through informatics based training and education. This involves simulation, educational gaming, and health-focused and objective training metrics. Within this JPC, the Combat Casualty Training Initiative supports the testing and evaluation of innovative medical simulation technologies with the goal of improving healthcare access, availability, continuity, cost effectiveness, quality, and patient safety through improved decision-making. 2 - The Military Operational Medicine JPC supports the testing and evaluation of real-time physiological (normal function of living organisms and their parts) status monitoring in order to provide actionable patient information. 3- The Combat Casualty Care JPC seeks Food and Drug Administration (FDA) approval of methods, drugs and devices through human clinical trials. Within this JPC, advanced product development to improve the quality of care is ongoing within the areas of hemorrhage, shock, and coagulopathy of trauma. In addition, the traumatic brain injury (TBI) neurotrauma and brain dysfunction area is validating TBI therapeutics and testing new imaging techniques, battlefield devices for operational decision making, and behavioral physiologic assessment tools for mild TBI. 4- The Clinical Rehabilitation Medicine JPC seeks FDA approval of fast-acting, easily dispensed oral battlefield pain management products that have minimal side effects.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD)	13.919	17.180	14.464
Description: GDF-Medical Products and Support Systems Development: Activities conducted are intended to support system development and demonstration prior to initial full rate production and fielding of medical commodities delivered from 0604110HP (Medical Products Support and Advanced Concept Development). Development and demonstration activities will be conducted in the following areas: medical modeling and simulation systems for training/education/treatment, rapid screening for fresh whole blood, and Spray Dried Plasma and TBI biomarker (biological indicator) point of care devices.			
FY 2016 Accomplishments: Medical simulation and information sciences efforts continued evaluations of the effectiveness of commercially available or advanced prototype simulation systems and currently used live tissue training models. This work supports the knowledge product researching the reduction and refinement of the use of live tissue for training. Combat casualty care hemorrhage and resuscitation research: Completed a human safety study in humans in support of a FDA Biologic License Application for a spray-dried plasma product. For the spray-dried plasma product, coordinated preparation of a			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 375A / *GDF-Medical Products and Support System Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
human safety, dose and initial efficacy trial; initiated planning for clinical trials to confirm safety and effectiveness of the product in diverse populations. Combat casualty care neurotrauma research: Continued clinical trial to evaluate novel biomarker-based TBI diagnostics and point of care diagnostic devices. ***FY 2017 Plans:*** Medical simulation and information sciences efforts work toward updating several serious medical games and transitioning them to the advanced developer. Military operational medicine is validating, through end-user field testing, a system-on-a-chip ultra-low power physiologic status monitoring system. Combat casualty care hemorrhage and resuscitation research: For the spray-dried plasma product, initiating clinical trials to confirm safety and effectiveness in diverse populations. Combat casualty care neurotrauma research: Continued clinical trial to evaluate novel biomarker-based TBI diagnostics and point of care diagnostic devices; downselecting a point of care diagnostic device. ***FY 2018 Plans:*** Medical simulation and information sciences efforts will support the Special Operation Forces (SOF) with additional training for prolonged field care to support anti access and area denial requirements. Military operational medicine will continue the testing of a real-time physiological status monitoring system that integrates refined algorithms and respective sensors into actionable real-time physiological status, health, and readiness information. Combat casualty care hemorrhage and resuscitation research: For the spray-dried plasma product, will continue clinical trials to confirm safety and effectiveness in diverse populations. Will continue human clinical studies to confirm safety and effectiveness of valproic acid, a drug to prolong survival following severe hemorrhage. Combat casualty care neurotrauma research: Will support validation of downselected point of care device to assess and monitor TBI casualties in the far forward field environment. Clinical and rehabilitative medicine will seek FDA approval for Sufentanil, a rapid acting pain medication with minimal side effects.			
Accomplishments/Planned Programs Subtotals	13.919	17.180	14.464

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 375A / *GDF-Medical Products and Support System Development*

D. Acquisition Strategy

Test and evaluate medical procedures and prototype devices in government-managed Phase 2 and Phase 3 clinical trials in order to gather data to meet military and regulatory (e.g., FDA, Environmental Protection Agency) requirements for production and fielding.

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, and quarterly and annual status reports and is subject to Program Office or Program Sponsor Representatives progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. In addition, Integrated Product Teams, if established for a therapy or device, will monitor progress in accordance with DoD Instruction 5000 series on the Operation of the Defense Acquisition System. The benchmark performance metric for transition of research supported in this PE will be the attainment of a maturity level that is typical of Technology Readiness Level 8 and/or the achievement of established Key Performance Parameters.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / *Medical Products and Support Systems Development*	Project (Number/Name) 399A / *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	25.334	0.790	0.774	0.755	-	0.755	0.874	0.935	0.954	0.973	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Army, the Hyperbaric Oxygen Therapy (HBO2) clinical trials focus on research related to the development of treatment modalities using HBO2 for chronic post-concussion syndrome after mild traumatic brain injury (mTBI). Three HBO2 human clinical trials were designed to evaluate the effectiveness of HBO2 treatments for Service members who have experienced one or more concussions and who are symptomatic at, or after, the time of post-deployment health reassessments: 1- A pilot phase II (narrow population safety and effectiveness) study of hyperbaric oxygen for persistent post-concussive symptoms after mild traumatic brain injury (HOPPS), 2- Brain Injury and Mechanisms of Action of Hyperbaric Oxygen for Persistent Post-Concussive Symptoms after Mild Traumatic Brain Injury (BIMA), and 3- Development of Normative Datasets for Assessments Planned for Use in Patients with Mild Traumatic Brain Injury (Normal). A fourth retrospective study, Long Term Follow-up (LTFU), is focused on the lessons learned from long-term follow-up of subjects enrolled in the Department of Defense (DoD) primary HBO2 trials. To support these protocols, four HBO2 study sites were established within the Military Health System. Each of the research sites consisted of a hyperbaric oxygen chamber enclosed in a mobile trailer, a second mobile trailer for testing and evaluation of the subjects, and a third subject staging trailer. This information is intended to inform DoD policy decisions regarding the use of HBO2 therapy as a treatment for mTBI.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Hyperbaric Oxygen Therapy Clinical Trial (Army)	0.790	0.774	0.755
Description: The HBO2 clinical trials are designed to test the effectiveness of HBO2 treatments for Service members who have experienced one or more concussions and who are symptomatic at, or after, the time of post-deployment health reassessments.			
FY 2016 Accomplishments: Completed data accession phase of two on-going HBO2 clinical trials (BIMA and Normal). Completed Subject Matter Expert (SME) analysis of brain scan data and monitoring devices (baseline Holter monitor, Eyetracker, electroencephalogram, individual and longitudinal computerized tomography, individual and longitudinal magnetic resonance imaging, and looming functional magnetic resonance imaging). Along with the LTFU study results, this information was published in a peer-reviewed journal special edition. The BIMA study outcomes data and comparative data from the Normal study subject population were submitted for SME evaluation. Continued development of the final clinical study report, statistical report, draft primary manuscript, and corresponding materials for scientific presentation and journal submissions.			
FY 2017 Plans: Continue collaboration with subject matters experts to complete the BIMA and Normal trial final clinical study report, statistical report, and primary manuscript. Draft clinical study and statistical reports for submission to the US Food and Drug Administration. Consolidate BIMA study data for inclusion in the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 399A / *Hyperbaric Oxygen Therapy Clinical Trial (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
system. Prepare manuscripts reporting the Normal study comparative findings. Finalize a meta-analysis that identified common trends and findings across the four DoD-sponsored trials evaluating HBO2 effects on mTBI. ***FY 2018 Plans:*** Submit the final clinical study and statistical reports for the BIMA/Normal studies to the FDA. Publish the BIMA / Normal study primary manuscript and other peer-reviewed manuscripts detailing outcome measure findings. Transfer mTBI study data into the FITBIR informatics system. In response to positive meta-analysis findings, develop and implement a multi-Service protocol designed to evaluate a potential dose-response improvement in combat-related PTSD symptoms secondary to HBO2 exposure. Beyond targeting identification of an optimal oxygen exposure dose, this protocol will assess the time to onset, duration and magnitude of the symptom improvements previously seen. Concurrently, the protocol will evaluate the relative contribution of placebo and Hawthorne influences previously ascribed to the DoD-sponsored HBO2 trials.			
Accomplishments/Planned Programs Subtotals	0.790	0.774	0.755

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

The acquisition outcome of this effort is a knowledge product, with the results intended to inform DoD mTBI treatment and reimbursement policies. The decision to pursue FDA registration/off-label application of an existing drug-device combination product will be made as part of a formal decision by leadership after the DoD HBO2 trial results are reviewed. If future work using HBO2 proves beneficial in the treatment of PTSD this knowledge product would inform DoD treatment and reimbursement policies.

E. Performance Metrics

The HBO2 Program Management Office monitors the performance of contracts through review of monthly, yearly and final progress reports to ensure that milestones are met, deliverables will be transitioned on schedule and within budget and in accordance with DoD Instruction 5000. The HBO2 Executive Committee meets bi-monthly to evaluate the direction of the science, discuss future actions, and resolve any current or potential issues or areas of concern.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / *Medical Products and Support Systems Development*	Project (Number/Name) 500A / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
500A: *CSI - Congressional Special Interests*	12.150	0.881	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2016 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0605145 - Medical Products and Support Systems Development. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 465A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2016 Accomplishments:*** FY 2016 Plans: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0605145. Funds supported product testing for combat casualty care (Project 375A).	0.800	-
Congressional Add: 475A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2016 Accomplishments:*** FY 2016 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0605145. Funds supported efforts for the Hyperbaric Oxygen Therapy Clinical Trials (Project 399A).	0.081	-
Congressional Adds Subtotals	0.881	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605502DHA *I Small Business Innovation Research (SBIR) Program*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	168.337	72.915	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
470A: *Small Business Innovation Research (SBIR) (Army)*	161.415	63.404	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
470B: *Small Business Technology Transfer (STTR) Program*	6.922	9.511	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Small Business Innovation Research (SBIR) program was established in the Defense Health Program (DHP), Research, Development, Test and Evaluation (RDT&E) appropriation during FY 2001, and is funded in the year of execution. The objective of the DHP SBIR Program includes stimulating technological innovation, strengthening the role of small business in meeting Department of Defense (DoD) research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technological innovation, and increasing the commercial application of DoD-supported research and development results. The program funds small business proposals chosen to enhance military medical research and information technology research.

The Small Business Technology Transfer (STTR) program was established in the DHP, RDT&E appropriation during FY 2015, and is funded in the year of execution. The STTR Program, although modeled substantially on the SBIR Program, is a separate program and is separately financed. Central to the program is expansion of the public/private sector partnership to include the joint venture opportunities for small businesses and nonprofit research institutions. The unique feature of the STTR program is the requirement for the small business to formally collaborate with a research institution in Phase I and Phase II. STTR's most important role is to bridge the gap between performance of basic science and commercialization of resulting innovations. The mission of the STTR program is to support scientific excellence and technological innovation through the investment of Federal research funds in critical American priorities to build a strong national economy. The programs' goals are to stimulate technological innovation, foster technology transfer through cooperative research and development between small businesses and research institutions, and increase private sector commercialization of innovations derived from federal research and development.

Both the SBIR and STTR programs address the President's multi-agency science and technology priority of innovation in life sciences, biology, and neuroscience through coordination with the Joint Program Committees, which manage multi-Service DHP-sponsored research.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency					Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*		R-1 Program Element (Number/Name) PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*			
B. Program Change Summary ($ in Millions)	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**
Previous President's Budget	0.000	0.000	0.000	-	0.000
Current President's Budget	72.915	0.000	0.000	-	0.000
Total Adjustments	72.915	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	72.915	-			

Change Summary Explanation

FY 2016: Realignment to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+ $72.915 million) from the following DHP PEs:
DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (-$0.269 million);
DHP RDT&E, PE 0601117-Basic Operational Medical Research Sciences (-$0.555 million);
DHP RDT&E, PE 0602115-Applied Biomedical Technology (-$4.114 million);
DHP RDT&E, PE 0602787-Medical Technology (AFRRI) (-$0.091 million);
DHP RDT&E, PE 0603002-Advanced Technology (AFRRI) (-$0.023 million)
DHP RDT&E, PE 0603115-Medical Technology Development (-$16.531 million);
DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (-$7.469 million);
DHP RDT&E, PE 0605013-Information Technology Development (-$1.451 million);
DHP RDT&E, PE 0605023-Integrated Electronic Record (iEHR) (-$.248 million);
DHP RDT&E, PE 0605025-Theater Medical Information Program - Joint (TMIP-J) (-$0.762 million);
DHP RDT&E, PE 0605026-DoD Healthcare Management System Modernization (DHMSM) (-$33.583 million)
DHP RDT&E, PE 0605039- DoD Medical Information Exchange and Interoperability/Defense Medical Information Exchange (DMIX) (-$0.843 million);
DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (-$1.132 million);
DHP RDT&E, PE 0606105-Medical Program-Wide Activities (-$4.475 million);
DHP RDT&E, PE 0607100-Medical Products and Capabilities Enhancement Activities (-$1.304 million).

FY 2017: No Change.

FY 2018: No Change.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	Project (Number/Name) 470A / *Small Business Innovation Research (SBIR) (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
470A: *Small Business Innovation Research (SBIR) (Army)*	161.415	63.404	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Defense Health Agency (DHA) Small Business Innovation Research (SBIR) Program can participate in any of the three (FY.1, FY.2, and FY.3) Department of Defense (DoD) SBIR Broad Agency Announcements (BAA). The process begins with a call for topics to the Joint Program Committees (JPCs), multi-Service committees established to manage research, development, test and evaluation for DHA sponsored research. DHA SBIR topics are submitted directly to the US Army Medical Research and Materiel Command (USAMRMC) and then forwarded to the JPCs for review and internal ranking. Topic Authors brief their topics at a Topic Review Meeting attended by DHA Research& Development Directorate (J9) SBIR Program Director (PD) and personnel from the supporting USAMRMC offices. Approved DHA SBIR topics are published in DoD SBIR BAAs. Small businesses submit proposals against topics which are then evaluated by a Technical Evaluation Team (TET) made up of a Team Chief and Technical Evaluators. TETs recommend proposals for selection. All recommended proposals are reviewed by the JPCs and the DHA SBIR PD. Phase I proposal selections are announced and contract negotiations begin. Phase I contracts are awarded up to $150K for 6 months. Follow-on Phase II projects can be awarded up to $1M for 24 months. This process ensures the SBIR program addresses the multi-agency science and technology priority of innovation in life sciences, biology, and neuroscience.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Small Business Innovation Research (SBIR) Program	63.404	0.000	0.000
Description: The program funds small business proposals chosen to enhance military medical research and information technology research. The following reflects the FY16 research area topics sought for proposals. ***FY 2016 Accomplishments:*** For FY 2016, twelve DHP SBIR topics were developed for the 2016.1 DoD SBIR Solicitation. Funding for each topic was based on the technical merits of the proposals submitted. Topics included: 2016.1 DHP SBIR Topic DHP16-001 - Warrior Health Avatar. This DHP SBIR initiative funded research to develop and demonstrate a simulation framework and physiology based modeling tools of a Warfighter body that could enable definite assessment of his/her health status, physical and physiological performance, and injury trajectory by both the user and medical personnel using mobile computing platforms. This effort solicited a total of ten SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by Technical Evaluation Team (TET) evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made by August 2016.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	**Project (Number/Name)** 470A / *Small Business Innovation Research (SBIR) (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
2016.1 DHP SBIR Topic DHP16-002 - Severe Trauma Female Simulation Training System. This DHP SBIR initiative funded research to develop a realistic simulation-based training system to support the development of psychomotor (movement or muscular activity associated with mental processes) skills to treat severe trauma on female casualties at point of injury. This effort solicited a total of ten SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made by August 2016. 2016.1 DHP SBIR Topic DHP16-003 - Value Based Monitoring of Cycles of Care. This DHP SBIR initiative funded research to develop software algorithms that reuse existing Military Health System data derived from healthcare operations to assess patient health and performance outcomes for condition-specific cycles of care, and their associated costs, for the purpose of measuring value. This effort solicited a total of sixteen SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made August 2016. 2016.1 DHP SBIR Topic DHP16-004 - Automated Vision Tester Technology Development for Aircrew Clinical Vision Screening. This DHP SBIR initiative funded research to develop, demonstrate, and deliver a computer-based, automated vision tester capable of conducting a full range of clinical vision screening procedures for both near and far focus distances. This effort solicited a total of six SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made by August 2016. 2016.1 DHP SBIR Topic DHP16-005 - Iron Status Determination Point-of-Care Device. This DHP SBIR initiative funded research to develop a point-of-care device that analyzes the serum iron indicators from a limited amount of blood to determine a diagnosis within minutes. This effort solicited a total of seven SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made by August 2016. 2016.1 DHP SBIR Topic DHP16-006 - Diagnostic Device for Detecting Biomarkers of Early Multi-organ Injury in Saliva. This DHP SBIR initiative funded research to develop a salivary diagnostic system for existing, clinically qualified biomarkers (biological indicators) of toxic (i.e., chemically-induced) organ injury normally detectable in plasma and/or urine in standard clinical practice.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	**Project (Number/Name)** 470A / *Small Business Innovation Research (SBIR) (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
This effort solicited a total of 33 SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made by August 2016. 2016.1 DHP SBIR Topic DHP16-007 - Creating Sterile Water for Injection (SWFI) at/near Point of Injury (POI). This DHP SBIR initiative funded research to develop a hand-held, portable capability to generate small volumes of SWFI in austere locations to reconstitute dried plasma, dehydrated medications, and other freeze dried medicine at or near the POI. This effort solicited a total of 19 SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of four Phase I proposals were selected under this topic. Awards were made by August 2016. 2016.1 DHP SBIR Topic DHP16-008 - Selective Brain Cooling for Traumatic Brain Injury (TBI). This DHP SBIR initiative funded research to develop a selective brain cooling (SBC) device that provides measurable neuroprotective effects after a moderate or severe TBI by cooling the brain during the acute and sub-acute post-injury phase. This effort solicited a total of sixteen SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made by August 2016. 2016.1 DHP SBIR Topic DHP16-009 - Selective Aortic Arch Perfusion Technologies for Hemorrhage-induced Cardiac Arrest. This DHP SBIR initiative funded research to develop and refine active selective aortic occlusion and perfusion technology that addresses non-compressible torso hemorrhage, hemorrhage-induced traumatic cardiac arrest that is compatible with currently existing extra-corporeal life support systems. This effort solicited a total of three SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made by August 2016. 2016.1 DHP SBIR Topic DHP16-010 - Filtration Technologies for Bridge Dialysis in Austere Medicine. This DHP SBIR initiative funded research to develop and refine filtration technologies that bind serum potassium in the context of hyperkalemia (above normal serum potassium levels) induced by traumatic injury and acute kidney injury. This effort solicited a total of five SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made by August 2016.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	**Project (Number/Name)** 470A / *Small Business Innovation Research (SBIR) (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
2016.1 DHP SBIR Topic DHP16-011 - Device to Prevent Retained Hemothorax (collection of blood in the space between the chest wall and the lung). This DHP SBIR initiative funded research to develop a device that can replace or work with existing large bore (>28 French) chest tubes to help evacuate or prevent accumulation of blood in the chest space after chest trauma or chest surgery. This effort solicited a total of three SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made by August 2016. 2016.1 DHP SBIR Topic DHP16-012 - Genitourinary Tissue Repair, Restoration and Protection: Preserving Fertility and Function in Wounded Warriors. This DHP SBIR initiative funded research to develop methods that enable protection, repair and restoration that preserve continence, sexual function, fertility and hormonal balance in male and female Service members. This effort solicited a total of seven SBIR Phase I proposals. In FY 2016, proposals were accepted through the 2016.1 DoD SBIR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards were made by August 2016.			
FY 2017 Plans: FY 2017 Plans: For FY 2017, eleven DHA SBIR topics were developed for the 2017.1 DoD SBIR BAA. Funding for each topic was based on the technical merits of the proposals submitted. Topics included: 2017.1 DHA SBIR Topic DHA17-001 - Electro-Textile Medical Simulation. This DHA SBIR initiative will fund research to develop a medical simulation to model the impacts to e-textiles that coincide with bodily injury. Once established, to use the e-textile impact to infer bodily damage. The model will be based on the e-textile work performed by the Services; in particular the Revolutionary Fibers and Textiles Institute located at US Army's Natick Soldier Research Development and Engineering Center (NSRDEC). This effort solicited a total of one SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of one Phase I proposal was selected under this topic. Awards will be made by 30 September 2017. 2017.1 DHA SBIR Topic DHA17-002 - Self-Healing Elastomer for Medical Simulation & Training. This DHA SBIR initiative will fund research to develop lifelike synthetic self-healing material suitable for applications such as 3-D printing or continuous			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	**Project (Number/Name)** 470A / *Small Business Innovation Research (SBIR) (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
liquid interface production as examples for medical simulation physical trainer applications. It is desired that such simulated tissue enable self-sealing tissue such as vessels (e.g. veins, arteries, etc.) skin, or other simulated tissues/organs that may be punctured, cut (incision), and possibly even excised, to represent the simulation of wound closure and multiple additional uses. This effort solicited a total of ten SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of four Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.1 DHA SBIR Topic DHA17-003 - Dynamics for Warfighter Avatars with Complete Articulated Anatomy. This DHA SBIR initiative will fund research to design, develop and demonstrate computer software and data structures for adding articulated joints and natural motions to the US Army Research Institute of Environmental Medicine (USARIEM) avatars and create a graphical user interface for planning and activating avatar physical movement. Complete anatomy avatars have a broad future role in advanced training environments providing, for example, 'medically correct' immersive experiences, performance-related physiological modeling studies, and in simulations for the purpose of designing protective armor. This effort solicited a total of six SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of two Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.1 DHA SBIR Topic DHA17-004 - A Device to Rapidly Detect Coliform Bacteria and Escherichia Coli in Field Water Samples. This DHA SBIR initiative will fund research to develop a field-portable device to rapidly detect viable coliform bacteria and Escherichia coli (E. coli) in water samples. This effort solicited a total of thirty-one SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of four Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.1 DHA SBIR Topic DHA17-005 - Compression Garment with Embedded Electronics for Ambulatory Health and Performance Monitoring. This DHA SBIR initiative will fund research to develop and demonstrate a functional compression shirt with embedded electronics capable of physiological monitoring. The prototype e-garment should be both comfortable for the user as well as capable of collecting, storing and wirelessly transmitting acquired data with minimal distortion. This system will provide physiological health and performance state information allowing for improved safety and sustained work capacity. The focus of this topic is primarily on the integration necessary to exploit extant and emerging state of the art ultra-low power electronics and other government furnished technologies to produce a functional physiological monitoring system. This effort solicited a total of seventeen SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	**Project (Number/Name)** 470A / *Small Business Innovation Research (SBIR) (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of four Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.1 DHA SBIR Topic DHA17-006 - Development of Thermal Desorption (TD) Tube Sequential Sampler. This DHA SBIR initiative will fund research to develop a thermal desorption (TD) tube sequential sampler to aid in accomplishing comprehensive air sampling on predetermined or automatically initiated timelines to improve the identification of contaminant concentrations at a certain point of time. This effort solicited a total of eight SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of three Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.1 DHA SBIR Topic DHA17-007 - Noninvasive Monitor of Vascular Volume Fluid Shifts. This DHA SBIR initiative will fund research to develop a working monitor that quantifies serial/continuous measurements of vascular volume components to detect shifts of 2% in less than 1 hour. This effort solicited a total of ten SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of three Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.1 DHA SBIR Topic DHA17-008 - Self-Aligning Prosthetic Components. This DHA SBIR initiative will fund research to develop and demonstrate an automatic alignment tool for a prosthetic leg. This tool will generate objective measures to determine optimal alignment of the prosthesis and will provide real time feedback to the care provider and patient. This effort solicited a total of ten SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of four Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.1 DHA SBIR Topic DHA17-009 - Conformable Osteochondral Repair Platforms for Prevention of Post Traumatic Osteoarthritis. This DHA SBIR initiative will fund research to develop an osteochondral repair platform that is conformable to a wide variety of injury geometries without the need for pre-operative customization, that does not rely on any autologous tissue, and that is amenable to scalable manufacturing methods. This effort solicited a total of eleven SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	**Project (Number/Name)** 470A / *Small Business Innovation Research (SBIR) (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
were announced in March 2017. A total of four Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.1 DHA SBIR Topic DHA17-010 - Point of Injury Device to Maintain and Stabilize Moderate-Severe Traumatic Brain Injury (TBI) Casualties. This DHA SBIR initiative will fund research to develop a novel device for the stabilization of moderate to severe brain injury at point of injury/point of need that can be used by first responders in the deployed environment (medics and corpsmen). This effort solicited a total of fourteen SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of three Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.1 DHA SBIR Topic DHA17-011 - Point of Injury Therapy to Maintain and Stabilize Moderate-Severe Traumatic Brain Injury (TBI) Casualties. This DHA SBIR initiative will fund research to develop a novel treatment for the stabilization of moderate to severe brain injury at point of injury/point of need that can be used by first responders in the deployed environment (medics and corpsmen). This effort solicited a total of eight SBIR Phase I proposals. In FY 2017, proposals were accepted through the 2017.1 DoD SBIR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of four Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. ***FY 2018 Plans:*** No funding programmed. The DHA SBIR program is funded in the year of execution.			
Accomplishments/Planned Programs Subtotals	63.404	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Test and evaluate commercially developed prototypes funded by the SBIR program to ensure military and regulatory requirements are met prior to production and fielding, to include Food and Drug Administration licensure and Environmental Protection Agency registration.

E. Performance Metrics

The number of Phase I awards supporting innovative technology development. The number of Phase II and III awards leading to technology transition.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	**Project (Number/Name)** 470B / *Small Business Technology Transfer (STTR) Program*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
470B: *Small Business Technology Transfer (STTR) Program*	6.922	9.511	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Small Business Technology Transfer (STTR) is a program that expands funding opportunities in the federal innovation research and development arena. Central to the program is expansion of the public/private sector partnership to include the joint venture opportunities for small businesses and nonprofit research institutions. The unique feature of the STTR program is the requirement for the small business to formally collaborate with a research institution in Phase I and Phase II. STTR's most important role is to bridge the gap between performance of basic science and commercialization of resulting innovations. The program funds small business proposals that partner with a research institution, are technically meritorious, and enhance Joint Program Committee (JPC) research and development efforts. The DHA STTR Program can participate in any of the three (FY.A, FY.B, and FY.C) Department of Defense (DoD) STTR BAAs. The process begins with a call for topics to the JPCs. DHA STTR topics are submitted directly to US Army Medical Research and Materiel Command (USAMRMC) and then forwarded to the JPCs for review and internal ranking. Topic Authors brief their topics at a Topic Review Meeting attended by the DHA Research& Development Directorate (J9) STTR Program Director (PD)and personnel from the supporting USAMRMC offices. Approved DHA STTR topics are published in the DoD STTR BAA. Small businesses submit proposals against topics which are then evaluated by a Technical Evaluation Team (TET) made up of a Team Chief and Technical Evaluators. TETs recommend proposals for selection. All recommended proposals are reviewed by the JPCs and the DHA STTR PD. Phase I proposal selections are announced and contract negotiations begin. Phase I contracts are awarded up to $150K for 6 months. Follow-on Phase II projects can be awarded up to $1M for 24 months. This process ensures the STTR program addresses the multi-agency science and technology priority of innovation in life sciences, biology, and neuroscience.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Small Business Technology Transfer (STTR) Program	9.511	0.000	0.000
Description: STTR Program offers funding opportunities in federal research and development to small businesses. The program aims to stimulate technological innovation in DoD research and development, strengthen the role of small business in meeting DoD research and development needs, foster and encourage participation by minority and disadvantaged persons in technological innovation, and increase the commercial application of DoD-supported research or research and development results.			
FY 2016 Accomplishments: For FY 2016 (DHP STTR 16.A), one topic was developed for the 2016.A DoD STTR Solicitation. Funding for the topic was based on the merits of responses to the solicitation. The topic included: 2016.A DHP STTR Topic DHP16A-001 - Bio-Mathematical Models of Aggregated Tissues & Organ Properties. This DHP STTR initiative funded research to develop a preliminary framework for a bio-mathematical model to explain how human tissues interact/			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	**Project (Number/Name)** 470B / *Small Business Technology Transfer (STTR) Program*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
behave at their boundaries; develop a mathematical framework for translating this tissue interaction/behavior into predictive mathematical/biomechanical models able to represent tissue property transitions (e.g., muscle to tendon/ligament), aggregated tissues (connective, epithelial, muscular, and nervous), and systems of tissues/organ properties and behaviors. This effort solicited a total of four STTR Phase I proposals. In FY 2016, proposals were accepted through the 2016.A DoD STTR Solicitation pre-released in December 2015. Proposals were received in February 2016 followed by TET evaluations in March 2016. Phase I proposal selections were announced in April 2016. A total of three Phase I proposals were selected under this topic. Awards will be made by August 2016.			
FY 2017 Plans: For FY 2017, six DHA STTR topics were developed for the 2017.A DoD STTR BAA. Funding for each topic was based on the technical merits of the proposals submitted. Topics included: 2017.A DHA STTR Topic DHA17A-001 - Medical Electro-Textile Sensor Simulation. This DHA STTR initiative will fund research to develop a simulator to provide what-if scenarios to aid in developing smart combat uniform sensors and technology to record electromagnetic field activity of the war-fighter. The model will be developed for Joint use and is based on the e-textile work performed by the Services; in particular the Revolutionary Fibers and Textiles Institute located at the U.S. Army's Natick Soldier Research Development and Engineering Center (NSRDEC). This effort solicited a total of three STTR Phase I proposals. In FY 2017, proposals were accepted through the 2017.A DoD STTR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of three Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.A DHA STTR Topic DHA17A-002 - Smart Morphing Medical Moulage. This DHA STTR initiative will fund research to develop an advanced medical moulage technologies that can simulate an injury or pathology by morphing through a series of clinical states to provide stimulation of different senses to the trainee during a training scenario to confirm progression of the injury / pathology and/or to understand if iatrogenic errors or pathologies occurred due to treatment provided. As an example of a potential use case, a military medical specialist training for point-of-injury care might perform a lifesaving intervention and see the long-term impacts of that intervention. This effort solicited a total of five STTR Phase I proposals. In FY 2017, proposals were accepted through the 2017.A DoD STTR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of three Phase I proposals were selected under this topic. Awards will be made by 30 September 2017.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	**Project (Number/Name)** 470B / *Small Business Technology Transfer (STTR) Program*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
2017.A DHA STTR Topic DHA17A-003 - Principled Design of an Augmented Reality Trainer for Medics. This DHA STTR initiative will fund research to design, prototype, and validate an augmented reality training system that provides deployed medics with refresher training on common, life-critical procedures of combat medicine. This effort solicited a total of fifteen STTR Phase I proposals. In FY 2017, proposals were accepted through the 2017.A DoD STTR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of four Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.A DHA STTR Topic DHA17A-004 - Non-invasive Telemetric Assessment of Gut Microbiota Activity in Situ. This DHA STTR initiative will fund research to develop and validate an ingestible telemetric device for the non-invasive in vivo measurement of bacterial metabolite production within the human gastrointestinal (GI) tract. This effort solicited a total of two STTR Phase I proposals. In FY 2017, proposals were accepted through the 2017.A DoD STTR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of one Phase I proposal was selected under this topic. Awards will be made by 30 September 2017. 2017.A DHA STTR Topic DHA17A-005 - Wireless Non-Invasive Advanced Control of Microprocessor Prostheses and Orthoses. This DHA STTR initiative will fund research to develop and demonstrate a non-invasive technology to wirelessly control a microprocessor prosthetic foot or hand, or upper or lower limb microprocessor controlled orthosis. The technology must be able to be used within a prosthetic socket and extend beyond the socket for patients who do not use a socket (e.g. osseointegration) and to harness proximal information (e.g. knee, thigh, and hip information for patients with transtibial amputation). This effort solicited a total of two STTR Phase I proposals. In FY 2017, proposals were accepted through the 2017.A DoD STTR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of two Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. 2017.A DHA STTR Topic DHA17A-006 - Medical Device to Assess the Viability of Tissue Prior to Skin Grafting. This DHA STTR initiative will fund research to develop, design, and demonstrate new technology that will allow surgeons to precisely, quickly, and objectively assess the viability of tissue in order to evaluate the effectiveness of the debridement (excision) of necrotic tissue prior to skin grafting. This effort solicited a total of eleven STTR Phase I proposals. In FY 2017, proposals were accepted through the 2017.A DoD STTR BAA pre-released in November 2016. Proposals were received in February 2017 followed by Technical			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605502DHA / *Small Business Innovation Research (SBIR) Program*	**Project (Number/Name)** 470B / *Small Business Technology Transfer (STTR) Program*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Evaluation Team (TET) evaluations in March 2017. Phase I proposal selections were announced in March 2017. A total of three Phase I proposals were selected under this topic. Awards will be made by 30 September 2017. ***FY 2018 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	9.511	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Test and evaluate commercially developed prototypes funded by the STTR program to ensure military and regulatory requirements are met prior to production and fielding, to include Food and Drug Administration licensure and Environmental Protection Agency registration.

E. Performance Metrics

The number of Phase I awards supporting innovative technology development. The number of Phase II and III awards leading to technology transition.

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Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0606105DHA *I Medical Program-Wide Activities*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	193.416	51.811	58.410	69.191	-	69.191	63.755	67.219	68.563	69.934	Continuing	Continuing
305T: *USAMRIID IO&T (Army)*	73.904	17.002	2.915	13.708	-	13.708	0.455	0.000	0.000	0.000	Continuing	Continuing
368A: *Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)*	18.869	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
397T: *USAMRICD IO&T (Army)*	35.598	0.095	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
401A: *CONUS Laboratory Support Clinical Infrastructure (Army)*	19.237	4.602	5.064	5.155	-	5.155	5.253	5.358	5.465	5.574	Continuing	Continuing
432A: *OCONUS Laboratory Infrastructure Support (Army)*	27.661	11.549	11.502	11.419	-	11.419	13.218	14.144	14.427	14.715	Continuing	Continuing
433A: *NMRC Biological Defense Research Directorate (BDRD) (Navy)*	10.328	2.323	2.148	2.968	-	2.968	3.109	5.163	5.266	5.371	Continuing	Continuing
442A: *USARIEM Pike's Peak IO&T (Army)*	0.186	0.000	0.234	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
600A: *CSI - Congressional Special Interests*	5.967	16.240	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
494A: *Medical Development (Lab Support) (Navy)*	0.000	0.000	36.547	35.941	-	35.941	41.720	42.554	43.405	44.274	Continuing	Continuing
376A: *GDF - Medical Program-Wide Activities*	1.666	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command receives funding for research infrastructure management support at select continental United States and outside the continental US laboratories and clinical trial sites; work is done in collaboration with DoD Military Treatment Facilities. This program element does not fund research. It funds the infrastructure support staff enabling research scientists to conduct bio-surveillance and early-to-late-stage clinical investigations into biologics, drugs, protectants, device technologies, and knowledge products. The funding provides for the sustainment of technical subject matter expertise, independent of the number of assigned projects, and the costs related to the initial outfitting and transition (IO&T) of research, development, test, and evaluation medical laboratories funded under multi-year military construction (MILCON) projects. These IO&T funds are designated as appropriations other than MILCON.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0606105DHA *I Medical Program-Wide Activities*

The Office of the Assistant Secretary of Defense for Health Affairs (Force Health Protection & Readiness) receives funds to provide management support for research projects at Pacific Joint Information Technology Center (P-JITC).

For the Navy Bureau of Medicine and Surgery, this program element includes facility operational funding for the Medical Biological Defense research sub-function of the Naval Medical Research Center (NMRC) Biological Defense Research Directorate (BDRD). The program mission is mandated by the Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense (JRO-CBRND) baseline capabilities assessment of chemical and biological passive defense. The primary function is research on countermeasures to biological threat agents, development of assays to detect biological threat agents, and bioforensic analysis of biological threat agents.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	41.567	58.410	69.191	-	69.191
Current President's Budget	51.811	58.410	69.191	-	69.191
Total Adjustments	10.244	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	16.240	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-5.996	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 600A: *CSI - Congressional Special Interests*		
Congressional Add: *476A – Program Increase: Restore Core Research Funding Reduction (Army)*	1.476	-
Congressional Add: *466A - GDF-Restore Core Medical Program-Wide Activities (Army)*	11.100	-
Congressional Add: *476C – Program Increase: Restore Core Research Funding Reduction (Navy)*	3.664	-
Congressional Add Subtotals for Project: 600A	16.240	-
Congressional Add Totals for all Projects	16.240	-

Change Summary Explanation

FY 2016: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0606105-Medical Program-Wide Activities (+$16.240 million).

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0606105DHA *I Medical Program-Wide Activities*

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0606105-Medical Program-Wide Activities (-$4.502 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+ $4.502 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0603115-Medical Technology Development (-$38.211 million) to DHP RDT&E, PE 0606105-Medical Program-Wide Activities (+$38.211 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) PE 0606105-Medical Program-Wide Activities (-$5.191 million) to DHP O&M, BAG 3 - Private Sector Care (+$5.191 million).

FY 2017: Pike's Peak Investment, PE 0606105-Medical Program-Wide Activities (+$0.234 million).

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / *Medical Program-Wide Activities*	Project (Number/Name) 305T / *USAMRIID IO&T (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
305T: *USAMRIID IO&T (Army)*	73.904	17.002	2.915	13.708	-	13.708	0.455	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding supports the initial outfitting and transition (IO&T) costs associated with military construction (MILCON) for the US Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: USAMRIID IO&T (Army)	17.002	2.915	13.708
Description: US Army Medical Research Institute of Infectious Diseases in Fort Detrick, Maryland, IO&T costs associated with MILCON. ***FY 2016 Accomplishments:*** The FY 2016 USAMRIID IO&T program reflected the phased requirements based on construction progress one year in advance of the scheduled Beneficial Occupancy Date (BOD) and initiation of safety and Center for Disease Control (CDC) certifications. Initial outfitting equipment procurement was contracted from equipment listings based on delivery lead time, building placement, and installation. FY 2016 transition costs were the incremental fiscal year requirements for operations that support this multi-year MILCON project. Funds provided for personnel, travel, planning and acquisition support, any remaining movement support for materiel from the old to new or intermediate facility sites and increased phased dual occupancy costs of old and new sites. ***FY 2017 Plans:*** The FY 2017 USAMRIID IO&T program reflects the phased requirements based on construction progress as the building reaches BOD and begins the safety and CDC certification process. FY 2017 transition costs are the incremental fiscal year requirements for operations that support this multi-year MILCON project. Funds provide for personnel, travel, planning and acquisition support, any remaining movement support for materiel from the old to new or intermediate facility sites. Funds support initial relocation of personnel, equipment, and research products to the USAMRIID Replacement Facility. ***FY 2018 Plans:*** The FY 2018 USAMRIID IO&T program reflects the phased requirements as safety and CDC certification activities will continue to completion. FY 2018 costs will cover decommissioning costs of the existing USAMRIID facilities, the turn in and clean up of hazardous material, chemical material, and the decontamination of existing laboratory spaces. Funds will also be used to support the final relocation of personnel, equipment, and research products to the USAMRIID Replacement Facility.			
Accomplishments/Planned Programs Subtotals	17.002	2.915	13.708

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 305T / *USAMRIID IO&T (Army)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metric includes completed and documented analysis by the performer reflecting program execution and completion dates based on approved phasing.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 368A / *Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
368A: *Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)*	18.869	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Pacific Joint Information Technology Center (Pacific JITC) (DHA HIT Directorate) was established to rapidly research, test and develop Warfighter medical solutions and products, through pilot projects or prototypes that provide mission critical value and actionable information to the DoD, including Services, combatant commanders, and the Department of Veterans Affairs.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)	0.000	0.000	-
Description: Management support for research projects at Pacific Joint Information Technology Center (JITC). ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metric includes completed and documented analysis by the performer reflecting program execution and completion dates based on approved phasing.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / *Medical Program-Wide Activities*	Project (Number/Name) 397T / *USAMRICD IO&T (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
397T: *USAMRICD IO&T (Army)*	35.598	0.095	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding supports the initial outfitting and transition (IO&T) costs associated with military construction (MILCON) for the US Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, Maryland.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: USAMRICD IO&T (Army)	0.095	0.000	0.000
Description: The USAMRICD, Aberdeen Proving Ground, Maryland, IO&T costs associated with MILCON. ***FY 2016 Accomplishments:*** For FY 2016 the USAMRICD IO&T program reflected the final phased requirements based on construction completion. FY 2016 transition costs reflected the incremental requirements for operations that supported this multi-year MILCON project. Funds were used to provide for health facilities planning personnel, continued decommissioning characterization for chemical and radiological decontamination, and any remaining commissioning and transition costs. ***FY 2017 Plans:*** No funding programmed. ***FY 2018 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	0.095	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metrics include completed and documented analysis by the performer reflecting program execution and completion dates based on approved phasing. Successful establishment of a sufficient infrastructure will result in close coordination and cooperation between the research, development, test and evaluation community, Clinical Investigation Program, Military Treatment Facilities, and Defense Centers of Excellence communities with the initiation of new collaborative clinical studies and trials.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 401A / *CONUS Laboratory Support Clinical Infrastructure (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
401A: *CONUS Laboratory Support Clinical Infrastructure (Army)*	19.237	4.602	5.064	5.155	-	5.155	5.253	5.358	5.465	5.574	Continuing	Continuing

A. Mission Description and Budget Item Justification

Continental United States Laboratory Infrastructure Support funding provides infrastructure and management support for selected laboratories and research sites, enabling basic to late stage clinical investigations on medical products through collaborative efforts with the Military Health System's (MHS) Military Treatment Facilities (MTFs). MTFs provide access to the patient populations who will benefit the most from the medical products and capabilities being developed. The funds support the retention of technical subject matter expertise, independent of the number of assigned projects. The infrastructure funds also support Institutional Review Board functions, research technical support, statistical support, grant writing assistance, and other essential functions for maintaining research in MTFs. The funds do not support research, but provide the infrastructure support enabling MTF investigators to compete for research, development, test, and evaluation (RDT&E) research funds.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: CONUS Laboratory Support Clinical Infrastructure (Army)	4.602	5.064	5.155
Description: Management support for research infrastructure at select laboratories and research sites that conduct basic to late-stage clinical research and evaluation of investigational products, such as biologics, drugs, and devices to treat/prevent polytrauma (multiple traumatic injuries), through collaborative efforts with the MHS MTFs.			
FY 2016 Accomplishments: Supported efforts for military research. These efforts included support staff engaging in multiple clinical investigations and performing critical roles in research subject engagement, development and review of research protocols, and the creation, analysis and, communication of research data. Examples of the clinical research specialties supported by the program are: clinical research associate, study coordinator, human subjects protection scientist, budget analyst, computer information technology and management specialist, biomedical scientist/molecular biologist, statistician, database manager, biostatistics/bioinformatics analyst, biobank manager, research assistant, and clinical research coordinator. Efforts with the funding included: support for clinical investigations, submission for external funding applications, sustainment of a Clinical Investigation Committee to review research protocols and provide research support services, solicitation of collaborative research partnerships with non-federal organizations, utilization of funding opportunities database to assist MTF investigators, and identification of ways to improve submission competitiveness.			
FY 2017 Plans: Support efforts for military research. These efforts include support staff engaged in multiple clinical investigations and performing critical roles in research subject engagement, development and review of research protocols, and the creation, analysis,			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 401A / *CONUS Laboratory Support Clinical Infrastructure (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
and communication of research data. Examples of the clinical research specialties supported by the program are: clinical research associate, study coordinator, human subjects protection scientist, budget analyst, computer information technology and management specialist, biomedical scientist/molecular biologist, statistician, database manager, biostatistics/bioinformatics analyst, biobank manager, research assistant, and clinical research coordinator. Efforts with the funding include: support for clinical investigations, submission for external funding applications, sustainment of a Clinical Investigation Committee to review research protocols and provide research support services, solicitation of collaborative research partnerships with non-federal organizations, utilization of funding opportunities database to assist MTF investigators, and identification of ways to improve submission competitiveness. ***FY 2018 Plans:*** Will support efforts for military medical research. These efforts will include support staff engaged in multiple clinical investigations and performing critical roles in research subject engagement, development and review of research protocols, and the creation, analysis, and communication of research data. Examples of the clinical research specialties to be supported by the program are: clinical research associate, study coordinator, human subjects protection scientist, budget analyst, computer information technology and management specialist, biomedical scientist/molecular biologist, statistician, database manager, biostatistics/ bioinformatics analyst, biobank manager, research assistant, and clinical research coordinator. Efforts with the funding will include: support for clinical investigations, submission for external funding applications, sustainment of a Clinical Investigation Committee to review research protocols and provide research support services, solicitation of collaborative research partnerships with non-federal organizations, utilization of funding opportunities database to assist MTF investigators, and identification of ways to improve submission competitiveness.			
Accomplishments/Planned Programs Subtotals	4.602	5.064	5.155

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metrics include completed and documented analysis by the performer reflecting program execution and completion dates based on approved phasing. Successful establishment of a sufficient infrastructure will result in close coordination and cooperation between the RDT&E community, Clinical Investigation Program, MTFs, and Defense Centers of Excellence communities with the initiation of new collaborative clinical studies and trials.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 432A / *OCONUS Laboratory Infrastructure Support (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
432A: *OCONUS Laboratory Infrastructure Support (Army)*	27.661	11.549	11.502	11.419	-	11.419	13.218	14.144	14.427	14.715	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Outside of the Continental United States (OCONUS) Laboratory Infrastructure Support provides management support for research infrastructure at selected overseas laboratories and research sites that conduct biosurveillance and basic to late-stage clinical research and evaluation of investigational products, such as biologics, drugs, protectants, technologies, and knowledge products to treat/prevent infectious diseases for the purpose of protecting the Warfighter; this is accomplished through collaborative efforts with the respective host nation governments. These sites are the US Army Medical Research Directorate-Kenya (USAMRD-K) in Nairobi, Kenya, the US Army Medical Research Directorate-Georgia (USAMRD-G) in Tbilisi, Georgia, and the US Army Medical Directorate-Armed Forces Research Institute of Medical Sciences (USAMD-AFRIMS) in Bangkok, Thailand. USAMRD-G is the newest laboratory, and provides support in the Caucasus region, similar to that provided by the laboratories in Kenya and Thailand to East Africa and Southeast Asia regions.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: OCONUS Laboratory Infrastructure Support (Army)	11.549	11.502	11.419
Description: Management support for research infrastructure at selected overseas laboratories and research sites is integral to support the development and testing of improved means of predicting, detecting, preventing, and treating infectious disease threats to the US military, as well as support for surveillance, training, research, and response activities for emerging infectious disease threats that could affect Service members in those regions. Supported OCONUS laboratories are the AFRIMS in Bangkok, Thailand; the USAMRD-K in Nairobi, Kenya; and the USAMRD-G in Tbilisi, Georgia.			
FY 2016 Accomplishments: Infrastructure funding costs for USAMD-AFRIMS, USAMRD-K, and USAMRD-G laboratories consisted of administration and infrastructure support, which sustained medical research platforms for surveillance, testing, and evaluation of products to inform the development of interventions for military-relevant endemic diseases.			
FY 2017 Plans: Infrastructure funding costs for USAMD-AFRIMS, USAMRD-K, and USAMRD-G laboratories consist of administration and infrastructure support, which sustain medical research platforms for surveillance, testing, and evaluation of products to inform the development of interventions for military-relevant endemic diseases. Sustainment costs include resource management, logistics, safety, information technology activities, salaries, utilities, maintenance, transportation, shipping, vehicle maintenance and generator fuel.			
FY 2018 Plans:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 432A / *OCONUS Laboratory Infrastructure Support (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Infrastructure funding costs for USAMD-AFRIMS, USAMRD-K, and USAMRD-G laboratories will consist of administration and infrastructure support, which will sustain medical research platforms for surveillance, testing, and evaluation of products to inform the development of interventions for military-relevant endemic diseases. Sustainment costs will include resource management, logistics, safety, information technology activities, salaries, utilities, maintenance, transportation, shipping, vehicle maintenance and generator fuel.			
Accomplishments/Planned Programs Subtotals	11.549	11.502	11.419

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metrics include documented analysis reflecting program execution of sustainment and modernization of the administration and infrastructure support required for general research, test, and evaluation at the laboratories in Kenya, Thailand, and Georgia.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / *Medical Program-Wide Activities*	Project (Number/Name) 433A / *NMRC Biological Defense Research Directorate (BDRD) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
433A: *NMRC Biological Defense Research Directorate (BDRD) (Navy)*	10.328	2.323	2.148	2.968	-	2.968	3.109	5.163	5.266	5.371	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Navy Bureau of Medicine and Surgery, this program element (PE) includes funds for the Medical Biological Defense research sub-function of the Naval Medical Research Center (NMRC) Biological Defense Research Directorate (BDRD) that relocated to Fort Detrick, Maryland under the Base Re-Alignment and Closure (BRAC) Commission 2005. Operational costs are significant by virtue of being at Fort Detrick, a highly secure National Interagency Biodefense Campus (NIBC). Uninterrupted utilities to all buildings on NIBC are provided by a Central Utility Plant (CUP) whose capacity all partners on the NIBC are required to buy into. The annual projected costs are distributed amongst the partners based on square feet and number of occupants of the building. Further, the NIBC campus is a fenced physical location with Entry Control Points (ECP). The partners on the campus, therefore, are required to pay for the guard force manning their ECP.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: NMRC Biological Defense Research Directorate (BDRD) (Navy)	2.323	2.148	2.968
Description: Funding for this project code provides core funding for facility and security requirements in support of Biological Defense Research. The remainder of the program is sustained by the competitive acquisition of research funding. ***FY 2016 Accomplishments:*** FY16 funding was used for the Central Utility Plant, Entry Control Points Security Force and operational costs necessary to achieve the mission critical functions of BW agent detection, analysis, and deployable BW diagnostic lab service. ***FY 2017 Plans:*** Provide funding for the Central Utility Plant, Entry Control Points Security Force and operational costs necessary to achieve the mission critical functions of BW agent detection, analysis, and deployable BW diagnostic lab service. ***FY 2018 Plans:*** Provide funding for the Central Utility Plant, Entry Control Points Security Force and operational costs necessary to achieve the mission critical functions of BW agent detection, analysis, and deployable BW diagnostic lab service.			
Accomplishments/Planned Programs Subtotals	2.323	2.148	2.968

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 433A / *NMRC Biological Defense Research Directorate (BDRD) (Navy)*

D. Acquisition Strategy

N/A

E. Performance Metrics

Metrics include timely delivery of targeted funding support for BDRD operations, required to meet mission of developing and deploying BW assays, therapeutics, forensic analysis, and BW diagnostic lab services in response to science sponsor timelines.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / *Medical Program-Wide Activities*	Project (Number/Name) 442A / *USARIEM Pike's Peak IO&T (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
442A: *USARIEM Pike's Peak IO&T (Army)*	0.186	0.000	0.234	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding supports the initial outfitting and transition (IO&T) research, development, test and evaluation (RDT&E) costs associated with military construction (MILCON) for the US Army Research Institute of Environmental Medicine (USARIEM) at Pike's Peak, Colorado.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: USARIEM Pike's Peak IO&T (Army)	0.000	0.234	0.000
Description: Supports the initial outfitting and transition (IO&T) research, development, test and evaluation (RDT&E) costs associated with MILCON for the US Army Research Institute of Environmental Medicine (USARIEM) at Pike's Peak, Colorado. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** The associated MILCON project for replacing the US Army Research Institute of Environmental Medicine (USARIEM) at Pike's Peak, Colorado was cancelled in FY17. Associated IO&T funds will not be utilized. ***FY 2018 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.234	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metric includes completed and documented analysis by the performer reflecting program execution and completion dates based on approved phasing.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / *Medical Program-Wide Activities*	Project (Number/Name) 600A / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
600A: *CSI - Congressional Special Interests*	5.967	16.240	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2016 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0606105 - Medical Program-Wide Activities. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 476A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative was directed toward DHP core research initiatives in PE 0606105. Funds supported the OCONUS Laboratories (Project 432A) and USAMRIID IO&T (Project 305T).	1.476	-
Congressional Add: 466A - GDF-Restore Core Medical Program-Wide Activities (Army) ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative was directed toward DHP core research initiatives in PE 0606105. Funds supported the CONUS Laboratory Support Clinical Infrastructure (401A) and an upgrade to the Walter Reed Army Institute of Research Pilot Bioproduction Facility.	11.100	-
Congressional Add: 476C – Program Increase: Restore Core Research Funding Reduction (Navy) ***FY 2016 Accomplishments:*** FY 2016 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0606105. Funds supported the NMRC Biological Defense Research Directorate (Project 433A) and Medical Development Laboratory Support (Project 494A).	3.664	-
Congressional Adds Subtotals	16.240	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 600A / *CSI - Congressional Special Interests*

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 494A / *Medical Development (Lab Support) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
494A: *Medical Development (Lab Support) (Navy)*	0.000	0.000	36.547	35.941	-	35.941	41.720	42.554	43.405	44.274	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Navy Bureau of Medicine and Surgery, this program element (PE) includes costs related to laboratory management and support salaries of government employees that are not paid from science/research competitively awarded funding. The Outside Continental U.S. (OCONUS) laboratories conduct focused medical research on vaccine development for Malaria, Diarrhea Diseases, and Dengue Fever. In addition to entomology, the labs focus on HIV studies, surveillance and outbreak response under the Global Emerging Infections Surveillance (GEIS) program, and risk assessment studies on a number of other infectious diseases that are present in the geographical regions where the laboratories are located. The CONUS laboratories conduct research on Military Operational Medicine, Combat Casualty Care, Diving and Submarine Medicine, Infectious Diseases, Environmental and Occupational Health, Directed Energy, and Aviation Medicine and Human Performance.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Medical Development (Lab Support) (Navy)	0.000	36.547	35.941
Description: Funding in this project code covers operating and miscellaneous support costs at RDT&E laboratories, including facility, equipment and civilian personnel costs that are not directly chargeable to RDT&E projects. Excluded costs include military manpower and related costs, non-RDT&E base operating costs, and military construction costs, which are included in other appropriate programs.			
FY 2016 Accomplishments: No Funding Programmed.			
FY 2017 Plans: Per Memorandum of Agreement signed 7 AUG 2015, funding realigned from PE 0603115 to PE 0606105, FY16 funding was $35.878. Continue to provide operating support for eight medical RDT&E labs across 15 research focus areas with the goal of developing products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter. Requested funding will enable the labs to meet or exceed science performance metric objectives.			
FY 2018 Plans:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 494A / *Medical Development (Lab Support) (Navy)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Continue to provide operating support for eight medical RDT&E labs across 15 research focus areas with the goal of developing products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter. Requested funding will enable the labs to meet or exceed science performance metric objectives.			
Accomplishments/Planned Programs Subtotals	0.000	36.547	35.941

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metrics include timely and proportionate distribution of funds to labs and product lines to optimize resource utilization in the development and evaluation of products that protect, treat, rehabilitate and enhance the performance of the Warfighter.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0606105DHA / *Medical Program-Wide Activities*	**Project (Number/Name)** 376A / *GDF - Medical Program-Wide Activities*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
376A: *GDF - Medical Program-Wide Activities*	1.666	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command receives funding for research infrastructure management support at select continental United States and outside the continental US laboratories and clinical trial sites. Work is done in collaboration with DoD Military Treatment Facilities. This project does not fund research. It funds the infrastructure support staff enabling research scientists to conduct bio-surveillance and early-to-late-stage clinical investigations into biologics, drugs, protectants, device technologies, and knowledge products. The funding provides for the sustainment of technical subject matter expertise, independent of the number of assigned projects, and the costs related to the initial outfitting and transition (IO&T) of research, development, test and evaluation medical laboratories funded under multi-year military construction (MILCON) projects. These IO&T funds are designated as appropriations other than MILCON.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: 376A: GDF – Medical Program-Wide Activities	0.000	0.000	-
FY 2016 Accomplishments: No Funding Programmed.			
FY 2017 Plans: No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0607100DHA *I Medical Products and Capabilities Enhancement Activities*

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
Total Program Element	53.833	16.052	14.998	13.438	-	13.438	15.714	16.819	17.215	17.619	Continuing	Continuing
377A: *GDF-Medical Products and Capabilities Enhancement Activities*	50.115	16.052	14.998	13.438	-	13.438	15.714	16.819	17.215	17.619	Continuing	Continuing
457A: *AF Advanced Technology Development – Rapid Technology Transition*	1.336	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
700A: *CSI - Congressional Special Interests*	2.382	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Products and Capabilities Enhancement Activities: Funds will support (1) developmental upgrades to medical systems and products that have been fielded, are routinely used in a fixed facility, or that have been approved for full-rate production and for which procurement funding is anticipated in the current fiscal year or subsequent fiscal years, (2) testing and evaluation supporting the enhancement of fielded or procured medical systems/products and medically-related information technology systems, (3) assessment of fielded medical products or medical practices in order to identify the need/opportunity for changes, and (4) analyses of clinical intervention outcomes to enhance and improve military unique Clinical Practice Guidelines. Efforts address the Military Health System Concept of Operations documents and follow-on Capabilities Based Assessments/Joint Capability Documents, appropriate Component requirements, legislative and Executive directives (e.g., National Research Action Plan, Precision Medicine Initiative, Office of Management and Budget Combat Casualty Care Assessment, National Defense Authorization Acts, etc.), and others as appropriate.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	17.356	14.998	14.938	-	14.938
Current President's Budget	16.052	14.998	13.438	-	13.438
Total Adjustments	-1.304	0.000	-1.500	-	-1.500
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.304	-			
• Cancer Moonshot	-	-	-1.500	-	-1.500

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0607100DHA *I Medical Products and Capabilities Enhancement Activities*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 700A: *CSI - Congressional Special Interests*		
Congressional Add: *467A – Program Increase: Restore Core Research Funding Reduction (GDF)*	0.000	-
Congressional Add Subtotals for Project: 700A	0.000	-
Congressional Add Totals for all Projects	0.000	-

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0607100-Medical Products and Capabilities Enhancement Activities (-$1.304 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$1.304 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) PE 0607100-Medical Products and Capabilities Enhancement Activities (-$2.291 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Caree (+$2.291 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0607100-Medical Products and Capabilities Enhancement Activities (-$0.358 million) to USU DHP RDT&E PE 0603115 Breast, GYN and Prostate Cancer Centers of Excellence (+$0.358 million).

FY 2018: Realignment from DHP RDTE PE 0607100-Medical Products and Capabilities Enhancement Activities, Project 377 GDF (-$1.500 million) to DHP RDTE PE 0603115-Medical Technology Development, Uniformed Services University, Project 478 Applied Proteogenomics Organization Learning and Outcomes (APOLLO) Consortium (+$1.500 million) to support the White House-directed Cancer Moonshot initiative.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0607100DHA / *Medical Products and Capabilities Enhancement Activities*	**Project (Number/Name)** 377A / *GDF-Medical Products and Capabilities Enhancement Activities*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
377A: *GDF-Medical Products and Capabilities Enhancement Activities*	50.115	16.052	14.998	13.438	-	13.438	15.714	16.819	17.215	17.619	Continuing	Continuing

A. Mission Description and Budget Item Justification

The goal of the Medical Products and Capabilities Enhancement Activities is to test, evaluate, and support enhancement of existing medical products and medically-related IT systems within the Joint Program Committee (JPC) research areas of Medical Simulation and Information Sciences, Infectious Diseases, Combat Casualty Care, Military Operational Medicine, and Clinical and Rehabilitative Medicine. Additionally, funding supports the investigation of clinical intervention outcomes to support, enhance, and improve militarily unique Clinical Practice Guidelines. Program Element (PE) 6.7 efforts are short-term, high-impact projects. It is an intramural research program focused on the evaluation of new commercial medical capabilities suitable for theater, the testing of a fielded capability to function in an expanded or altered operationally-relevant environment, and investigating the potential to incorporate emerging medical or non-medical technologies into fielded medical systems.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: 377A: GDF – Medical Products and Capabilities Enhancement Activities	16.052	14.998	13.438
Description: Provide support for developmental efforts to upgrade medical products and capabilities that have been fielded or have received approval for full rate production and anticipate production funding in the current or subsequent fiscal year.			
FY 2016 Accomplishments: 1- Analyzed data on the population prevalence of a form of CYP2D6, a drug-metabolizing enzyme which has been linked to malaria relapse following treatment with primaquine and provided recommendations on primaquine use to treat malarial relapse; 2- initiated patient enrollment in study to assess whether a current method of monitoring traumatic brain injury (TBI) patients may worsen clinical outcomes; 3- initiated patient enrollment on the effectiveness of the Defense and Veterans Brain Injury Center Progressive Return to Activity Clinical Recommendation Tool for Service members following concussion/mild TBI; 4- collected data for comparison of a commercially available device measuring injury specific biomarkers (biological indicators) of acute kidney injury versus the current standard of practice; 5- began subject recruitment for assessment on the use of a marksmanship trainer, the Conflict Kinetics (CK) Gunfighting Gym, as a potential tool/metric to measure neurocognitive (cognitive functions associated with particular areas of the brain) status/mental performance; 6- evaluated technologies designed to fabricate custom ear pieces for hearing protection; 7- collected retrospective data and began a prospective study evaluating the efficacy of a peripheral nerve block to correct heterotopic ossification (abnormal bone growth outside of the skeleton), which can occur after battlefield injuries, severe burn injuries and following amputation; 8- continued evaluations of junctional and extremity tourniquets to stop excessive bleeding; 9- evaluated commercial spatial mosquito repellents for efficacy in wind tunnel and semi-field tests to provide data to the Repellents Committee of the Armed Forces Pest Management Board; 10- designed improved, affordable versions of hoistable rescue litter that make patient securing procedure faster and easier and improve patient access; and 11- began evaluation of			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0607100DHA / *Medical Products and Capabilities Enhancement Activities*	**Project (Number/Name)** 377A / *GDF-Medical Products and Capabilities Enhancement Activities*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
commercially available surgical pneumatic tourniquets (used during orthopedic and plastic/reconstructive surgeries to produce a relatively bloodless operative field) for military operational suitability to inform selection of replacement for currently fielded discontinued models. ***FY 2017 Plans:*** Solicit, review, and make awards for intramural proposals consistent with the intent of PE 6.7. For previously funded efforts: continuing patient recruitment for a study assessing whether a current method of monitoring TBI patients may worsen clinical outcomes; continuing patient enrollment and data analysis on the Defense and Veterans Brain Injury Center Progressive Return to Activity Clinical Recommendation Tool for Service members following concussion/ mild TBI; continuing data collection on comparison of a commercially available device measuring injury specific biomarkers of acute kidney injury versus the current standard of practice; completing assessment and provide recommendations on the use of a marksmanship trainer, the CK Gunfighting Gym, as a potential tool/metric to measure neurocognitive status/mental performance and provide a plan to translate the tests designed for the larger CK platform to smaller platforms; continuing data collection on the efficacy of a peripheral nerve block during corrective surgery for heterotopic ossification, a condition which can occur after battlefield injuries, severe burn injuries, and following amputation; building and testing improved, affordable versions of hoistable rescue litter that will make patient securing procedure faster and easier and will improve patient access; completing the testing of commercially available surgical pneumatic tourniquets for military operational suitability and make a recommendation to replace currently fielded discontinued models; beginning adaptation of the current (paper) pain management workbook into an interactive, mobile application software (app) to increase accessibility and engagement among patients for optimizing pain management and treatment; initiate enrolling TBI patients to determine whether a commercially available, non-invasive cerebral blood flow monitor can predict progression of TBI, potentially transforming TBI care in deployed settings. ***FY 2018 Plans:*** Will solicit, review, and make awards for intramural proposals consistent with the intent of PE 6.7. For previously funded efforts: will continue patient recruitment and begin data analysis for a study assessing whether a current method of monitoring TBI patients may worsen clinical outcomes; will complete patient enrollment and continue data analysis on the Defense and Veterans Brain Injury Center Progressive Return to Activity Clinical Recommendation Tool for Service members following concussion/ mild TBI; will complete data collection and data analysis on comparison of a commercially available device measuring injury specific biomarkers of acute kidney injury versus the current standard of practice; will complete data collection and analysis on the efficacy of a peripheral nerve block during corrective surgery for heterotopic ossification, a condition which can occur after battlefield injuries, severe burn injuries, and following amputation; will complete adaptation of the current (paper) pain management workbook into an interactive, mobile app to increase accessibility and engagement among patients for optimizing pain management and treatment and will conduct patient usability testing of the app; will continue enrolling TBI patients and begin			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0607100DHA / *Medical Products and Capabilities Enhancement Activities*	**Project (Number/Name)** 377A / *GDF-Medical Products and Capabilities Enhancement Activities*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
data analysis to determine whether a commercially available, non-invasive cerebral blood flow monitor can predict progression of TBI, potentially transforming TBI care in deployed settings.			
Accomplishments/Planned Programs Subtotals	16.052	14.998	13.438

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

The PE 6.7 Program Manager solicits proposals annually with two submission deadlines. Civilian and military intramural DoD laboratory investigators are eligible to apply. Awardees may collaborate with extramural (e.g., academia or industry) entities. Submitted proposals undergo a two-level review – one technical and one programmatic. A technical assessment of the proposals is solicited from the respective subject matter experts within the JPCs and the advanced development community. Following this, a programmatic review is performed by senior Service experts representing the science and technology base and advanced development. After the programmatic review, funding recommendations are forwarded to the Director, Research, Development and Acquisition, Defense Health Agency or their designee for final approval prior to award.

E. Performance Metrics

Principal Investigators will provide quarterly reports and a final report. Performance is measured based on the number of products for which testing either certifies use in a given environment (e.g., sufficiently ruggedized, airworthiness testing) and/or results in a recommendation of a specific product, and delivery of an enhanced product or knowledge product. The benchmark performance metric for research supported in this PE will be the enhancement of a maturity level that is typical of TRL 9.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0607100DHA / *Medical Products and Capabilities Enhancement Activities*	**Project (Number/Name)** 457A / *AF Advanced Technology Development – Rapid Technology Transition*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
457A: *AF Advanced Technology Development – Rapid Technology Transition*	1.336	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Air Force - Medical Products and Capabilities Enhancement Activities: Funds support a developmental upgrade to a medical product that has been fielded and for which procurement funding is anticipated subsequent fiscal years.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: AF Advanced Technology Development – Rapid Technology Transition	0.000	0.000	-
Description: Provide support for developmental efforts to upgrade medical products and capabilities that have been fielded or have received approval for full rate production and anticipate production funding in the current or subsequent fiscal year. ***FY 2016 Accomplishments:*** Complete enhancements and modifications to the XSTAT-30 Advanced Junctional Non-Compressible Hemorrhage Control Agent product, submit data package to the FDA regulatory approval process for predicate devices and transition the enhanced device to military operational use. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

$1.1M FY15/17 Defense Health Program – Air Force Procurement funds

D. Acquisition Strategy

Cost-plus Fixed Fee contract award to performer via the Army-Natick Soldier Systems Research Development and Execution Center contracting activity.

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0607100DHA / *Medical Products and Capabilities Enhancement Activities*	Project (Number/Name) 700A / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
700A: *CSI - Congressional Special Interests*	2.382	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

No FY 2016 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0607100 - Medical Products and Capabilities Enhancement Activities.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 467A – Program Increase: Restore Core Research Funding Reduction (GDF)	0.000	-
FY 2016 Accomplishments: No Funding Programmed.		
Congressional Adds Subtotals	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A