Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	6.606	2.904	4.599	2.653	-	2.653	2.879	3.687	4.013	4.093	Continuing	Continuing
010A: *CSI - Congressional Special Interests*	0.000	0.315	1.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
240A: *Infectious Disease (USUHS)*	0.924	0.362	0.433	0.390	-	0.390	0.421	0.480	0.490	0.500	Continuing	Continuing
240B: *Military Operational Medicine (USUHS)*	2.835	1.111	1.330	1.154	-	1.154	1.251	1.479	1.509	1.539	Continuing	Continuing
240C: *Combat Casualty Care (USUHS)*	2.847	1.116	1.836	1.109	-	1.109	1.207	1.728	2.014	2.054	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 $295 million annually). Approximately 108 intramural research projects are active each year, including 25 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the fund of knowledge intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs.

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: PB 2017 Defense Health Agency	Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	2.836	3.599	3.653	-	3.653
Current President's Budget	2.904	4.599	2.653	-	2.653
Total Adjustments	0.068	1.000	-1.000	-	-1.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.315	1.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.247	-			
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-1.000	-	-1.000

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Project: 010A: *CSI - Congressional Special Interests*		
Congressional Add: *468A – Program Increase: Restore Core Research Funding Reduction (USUHS)*	0.315	1.000
Congressional Add Subtotals for Project: 010A	0.315	1.000
Congressional Add Totals for all Projects	0.315	1.000

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601101-In-House Laboratory Independent Research (-$0.247 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$0.247 million).

FY 2015: Restores core research funding to the DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (+$0.315 million).

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

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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)*

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).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
010A: *CSI - Congressional Special Interests*	0.000	0.315	1.000	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 2015	FY 2016
Congressional Add: 468A – Program Increase: Restore Core Research Funding Reduction (USUHS)	0.315	1.000
FY 2015 Accomplishments: FY 2015 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.		
FY 2016 Plans: 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	0.315	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
240A: *Infectious Disease (USUHS)*	0.924	0.362	0.433	0.390	-	0.390	0.421	0.480	0.490	0.500	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 $295 million annually). Approximately 108 intramural research projects are active each year, including 25 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the fund of knowledge intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs.

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 2015	FY 2016	FY 2017
Title: Infectious Disease	0.362	0.433	0.390

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 2015 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 vaccine strategies; analysis of the entry and egress of Cedar Virus a new species of Henipavirus; development of a cutaneous

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 2016 Plans:*** We will continue to investigate infectious diseases that impact soldiers from the standpoint of lost “man-days” to death. We recognize that infectious disease can severely hamper combat readiness and effectiveness, and therefore we will continue to concentrate our 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 2017 Plans:*** Efforts will continue within the Infectious Disease research area in FY 2017. 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	0.362	0.433	0.390

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
240B: *Military Operational Medicine (USUHS)*	2.835	1.111	1.330	1.154	-	1.154	1.251	1.479	1.509	1.539	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 $295 million annually). Approximately 108 intramural research projects are active each year, including 25 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the fund of knowledge intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs.

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 2015	FY 2016	FY 2017
Title: Military Operational Medicine	1.111	1.330	1.154
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 2015 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 within recent suicide deaths of active duty service members to aid in identification and prevention efforts; study of load and dual			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 2016 Plans:*** 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 2017 Plans:*** Efforts will continue within the Military Operational Medicine research area in FY 2017. 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	1.111	1.330	1.154

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
240C: *Combat Casualty Care (USUHS)*	2.847	1.116	1.836	1.109	-	1.109	1.207	1.728	2.014	2.054	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 $295 million annually). Approximately 108 intramural research projects are active each year, including 25 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the fund of knowledge intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs.

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 2015	FY 2016	FY 2017
Title: Combat Casualty Care	1.116	1.836	1.109
Description: Combat Casualty Care: Ischemia and reperfusion injury, traumatic brain and peripheral nerve injury, neural control of pain, endotoxic shock, cryotherapy, malignant hyperthermia, inflammation, soman induced neuropathology and wound healing.			
FY 2015 Accomplishments: Representative projects will include: investigation of synaptic plasticity in temporal lobe epilepsy and possible development of novel therapies; determination whether BMP-2 is a effective therapy to promotes recapitulation of the meninges surrounding the spinal cord; understanding the contribution of inflammation to post-injury loss of function after traumatic brain and spinal cord injury; investigate the underlying mechanisms involved in heart failure and drug-induced arrhythmias; utilizing mesenchymal progenitor cells (MPCs) from traumatized human tissue towards a better understanding of tissue genesis and the underlying mechanisms involved in both desirable and pathologic healing response ultimately identifying novel targets in the injury response that will lead to a more acceptable healing outcome; identifying how the formation of nerve cell circuits in the brain are affected by psychological stress and traumatic brain injury; utilizing PET imaging to characterize cell activity in spinal cord injury towards development of an optimized treatment; analysis of the underlying mechanisms responsible for the development of tolerance following the chronic use of opiates for severe pain; development of psychological interventions to be used with military health care providers who experience post-traumatic stress symptoms to prevent burn-out; and development of accurate millisecond-level assessment tools and computer based analyses to assist in the evaluation and assessment of traumatic brain injury.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
These studies also support the essential military mission by further exploring the mechanism of pain control for an established treatment; providing the groundwork for effective treatments to limit nerve damage and encourage regeneration; and identifying a possible cause for life-threatening complications due to the combination of exertion and injury common under heavy battlefield conditions ***FY 2016 Plans:*** 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 2017 Plans:*** Efforts will continue within the Combat Casualty Care research area in FY 2017. 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	1.116	1.836	1.109

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: PB 2017 Defense Health Agency	Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
Total Program Element	10.805	8.282	9.558	6.444	-	6.444	6.917	7.699	8.608	8.913	Continuing	Continuing
100A: *CSI - Congressional Special Interests*	2.237	1.578	2.161	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
371A: *GDF-Basic Operational Medical Research Sciences*	8.568	6.704	7.397	6.444	-	6.444	6.917	7.699	8.608	8.913	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 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 threatsthe 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, 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.

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency					Date: February 2016
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**
Previous President's Budget	7.481	7.397	9.417	-	9.417
Current President's Budget	8.282	9.558	6.444	-	6.444
Total Adjustments	0.801	2.161	-2.973	-	-2.973
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	1.578	2.161			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.777	-			
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-1.161	-	-1.161
• Restore USUHS Breast, GYN, and Prostate Cancer Centers of Excellence	-	-	-1.812	-	-1.812

Congressional Add Details ($ in Millions, and Includes General Reductions)	**FY 2015**	**FY 2016**
Project: 100A: *CSI - Congressional Special Interests*		
Congressional Add: *461A – Program Increase: Restore Core Research Funding Reduction (Army)*	1.578	2.161
Congressional Add Subtotals for Project: 100A	1.578	2.161
Congressional Add Totals for all Projects	1.578	2.161

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-$0.777 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$0.777 million).

FY 2015: Restore core research funding to the DHP RDT&E, PE 06011117-Basic Operational Medical Research Sciences (+$1.578 million).

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

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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*

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).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
100A: *CSI - Congressional Special Interests*	2.237	1.578	2.161	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2015 DHP Congressional Special Interest (CSI) funding was directed toward restoral of core research initiatives in 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 2015	FY 2016
Congressional Add: 461A – Program Increase: Restore Core Research Funding Reduction (Army)	1.578	2.161
FY 2015 Accomplishments: FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0601117. Funds supported basic research in military operational medicine (Project 371A).		
FY 2016 Plans: FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0601117. Funds supported basic research in military operational medicine (Project 371A).		
Congressional Adds Subtotals	1.578	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
371A: *GDF-Basic Operational Medical Research Sciences*	8.568	6.704	7.397	6.444	-	6.444	6.917	7.699	8.608	8.913	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 (JCIDS) process and sustainment of DoD 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 (JPC-2) research develops protection and treatment products for military relevant infectious diseases. Basic research efforts in this area support a task in bacterial diseases. 2- Military operational medicine (JPC-5) 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. Basic research efforts in this area support tasks in musculoskeletal injury; brain health and performance risk; behavioral health, wellness and resilience; warfighter physical performance; nutrition and weight balance; psychiatry and clinical psychology disorders; sensory performance, injury and protection; blunt, blast and accelerative injury; environmental toxicant exposure; and aircrew health and performance. 3- Combat casualty care (JPC-6) research is focused on optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through enroute and facility care. Basic research efforts in this area support the task for hemorrhage, shock, and coagulopathy (inability of blood to clot normally) of trauma.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Project 371 GDF – Basic Operational Medical Research Sciences	6.704	7.397	6.444
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 2015 Accomplishments: FY 2015 Accomplishments: Military infectious diseases research supported antimicrobial countermeasures to discover antibacterial agents for biofilms (a group of microorganisms in which cells stick to each other on a surface), characterize and detect multi-drug resistant organisms (MDROs), identify MDRO biomarkers (biological indicators of health outcomes and disease) and new targets. These laboratory studies helped provide an understanding of the mechanisms that make organisms infectious and mechanisms that render the human body response effective to prevent diseases caused by infectious agents.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Military operational medicine research continued studies to develop predictive models of repeated low level blast exposures in order to understand the mechanisms of injury and optimal exposure conditions, and identified potential biomarkers of pulmonary exposure to toxic substances from burn pit emissions, natural dust from Afghanistan, and the interactions between pollutants, which are associated with adverse health outcomes and lung disease. Studies in nutrition and dietary supplements assessed dietary status of different Service member populations. Additional studies identified novel targets for promotion of sleep quality, and refined algorithms that predict the effects of fatigue countermeasures, such as caffeine and naps, to optimize Warfighter physical and cognitive performance. Research continued in Posttraumatic Stress Disorder (PTSD) to identify and understand neural systems and mechanisms underlying PTSD vulnerability, disease progression, and identification of potential intervention targets for pharmacologic and stimulation approaches. These efforts supported the Precision Medicine Initiative. Combat casualty care basic research made progress towards identifying underlying pathophysiologic (functional changes associated with injury) mechanisms associated with coagulopathy of trauma, and towards identifying potential diagnostic and therapeutic targets of coagulopathy of trauma.			
FY 2016 Plans: FY 2016 Plans: Military infectious diseases research supports basic research laboratory studies in bacterial diseases prevention, treatment, and management to develop antibacterial agents targeting biofilms and MDRO s, and host and microbial biomarkers for early detection of infection. Outcomes from FY 2015-16 laboratory studies identify bacterial targets for prevention/treatment of diseases caused by bacterial agents. These studies are in alignment with the National Strategy for Combating Antibiotic Resistance. Military operational medicine research is identifying mechanisms and characterizing behavioral effects in small animal models resulting from low level repeated blast exposure, is characterizing 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. Starting studies to understand brain mechanisms associated with substance abuse problems that affect adult decision making and behavioral health. Beginning 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 official post-deployment mental diagnoses after high-conflict deployments. Starting studies to identify gender-specific factors that impact military task performance, defining minimal physical requirements for entry into physically demanding military occupations, investigating applications of novel interventions and their neurobiological impact via animal models to evaluate effectiveness in treating PTSD symptoms, conducting basic studies to define medical standards for noise injury criteria , and identifying novel interventions to promote sleep quality and nonpharmacological approaches to reduce the need for sleep in order to sustain Warfighter readiness. Studies to examine the effects of inadequate nutrition on gut microbiota composition and function. Studies to identify biomarkers of toxicity to complex chemical mixtures and particulates using an in vitro model system. Combat casualty care			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
basic research is identifying the molecular and cellular mechanisms involved in abnormal bleeding due to coagulopathy of trauma that occurs following severe trauma. The results from these studies will be used to generate diagnostics and therapeutic targets for further development. ***FY 2017 Plans:*** Military infectious diseases research will support multi-year basic research laboratory studies in bacterial diseases prevention, treatment, and management in discovery and development of antibacterial agents for biofilms and MDROs, detection of MDROs, and biomarkers. Successful approaches will be selected for continued funding. New studies will 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 characterize the biomechanical responses of brain tissue in animal models due to the indirect mechanism of blast waves (through the vasculature) using computational modeling that will guide the development of interventions for mitigating blast-induced brain injury. Will identify the role of individual and unit climate factors on aggression. Will begin studies to understand the basic mechanisms underlying psychological resilience to inform potential future intervention and assessment work. Will perform epidemiological studies to identify the nature of the substance abuse problem in the military and possible unique contributing and protective factors. Will continue PTSD research on genetic vulnerabilities, disease models and mechanisms, and identification of intervention targets for pharmacologic treatment approaches. Will establish mechanisms of electrical stimulation of the brain on wakefulness and cognitive processes. Will identify physiological factors that may affect the performance of female Warriors. Combat casualty care basic research will continue to identify the molecular and cellular mechanisms involved in abnormal bleeding due to coagulopathy of trauma that occurs following severe trauma. These findings will be used to generate diagnostic and therapeutic targets for further development. The Systems Biology Program in coagulopathy of trauma will be completed. Focus will shift toward exploiting findings to develop specific diagnostics and therapeutics for coagulopathy of trauma.			
Accomplishments/Planned Programs Subtotals	6.704	7.397	6.444

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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*

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-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: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	178.533	67.237	75.155	57.275	-	57.275	63.550	73.654	82.883	84.408	Continuing	Continuing
200A: *Congressional Special Interests*	70.883	25.303	16.904	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	0.000	3.150	2.860	-	2.860	2.142	1.857	1.949	1.989	Continuing	Continuing
306B: *Advanced Diagnostics & Therapeutics Research & Development (AF)*	6.912	2.708	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	0.000	1.728	1.757	-	1.757	1.987	2.025	2.066	2.107	Continuing	Continuing
306D: *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	0.000	0.000	1.728	1.758	-	1.758	1.988	2.026	2.066	2.108	Continuing	Continuing
372A: *GDF Applied Biomedical Technology*	92.328	32.677	43.579	43.462	-	43.462	49.639	58.724	67.148	68.357	Continuing	Continuing
447A: *Military HIV Research Program (Army)*	8.410	6.549	8.066	7.438	-	7.438	7.794	9.022	9.654	9.847	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 towards 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 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, 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 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, beginning in FY 2015, 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 2015, Congressional Special Interest funds were provided for Restore Core Research Funding Reduction. Because of the CSI annual structure, out-year funding is not programmed.

For the Air Force, this PE funds applied research which seeks to promote ‘omic’-informed personalized medicine, advanced diagnostic technologies and occupational toxicology with an emphasis on targeted prevention, diagnosis, and treatment. The delivery of pro-active, evidence-based, personalized medicine will improve health in Warfighters and beneficiaries by providing care that is specific to the situation and patient, to include preventing disease or injury, early and accurate diagnosis, and selection of appropriate and effective treatment. Personalized medicine will reduce morbidity, mortality, mission impact of illness/injury, and healthcare costs while increasing health and wellness of the AF population and efficiency of the healthcare system. This applied research supports multiple focus areas, each of which represents an identified barrier/gap which must be addressed for successful implementation of ‘omic’-informed personalized medicine. Focus areas for applied research include knowledge generation research; ethical legal and social issues/policy research; bioinformatics research; educational research; research for development of advanced genomic diagnostic system. For efforts supported by this program element, research will be pursued with the intent to support solutions that answer Air Force specific needs. During this process, the efforts of other government agencies in those areas will be assessed to avoid redundancy.

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency					Date: February 2016
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*			R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*		
B. Program Change Summary ($ in Millions)	**FY 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**
Previous President's Budget	47.898	58.251	68.797	-	68.797
Current President's Budget	67.237	75.155	57.275	-	57.275
Total Adjustments	19.339	16.904	-11.522	-	-11.522
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	25.303	16.904			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-1.785	-			
• SBIR/STTR Transfer	-4.179	-			
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-8.797	-	-8.797
• Restore USUHS Breast, GYN, and Prostate Cancer Centers of Excellence	-	-	-3.350	-	-3.350
• Rebalance Joint Program Committees	-	-	0.625	-	0.625

Congressional Add Details ($ in Millions, and Includes General Reductions)	**FY 2015**	**FY 2016**
Project: 200A: *Congressional Special Interests*		
Congressional Add: *426A – CSI - Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)*	0.000	5.833
Congressional Add: *462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)*	19.620	10.000
Congressional Add: *469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army)*	4.941	1.071
Congressional Add: *469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force)*	0.742	0.000
Congressional Add Subtotals for Project: 200A	25.303	16.904
Congressional Add Totals for all Projects	25.303	16.904

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).

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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 2016: Restore core research funding to the DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$16.904 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-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
200A: *Congressional Special Interests*	70.883	25.303	16.904	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

The FY 2015 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 2015	FY 2016
Congressional Add: 426A – CSI - Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)	0.000	5.833
FY 2015 Accomplishments: N/A		
FY 2016 Plans: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest program aimed to execute studies that inform the development of strategies to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, veterans, family members, caregivers, and communities. A key priority of the TBI/PH applied research program was to complement ongoing DoD 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 (identification of the nature and cause of an illness), treatment, and rehabilitation. Program announcements, programmatic reviews, Service-requested nominations, and ongoing studies that would benefit from program acceleration have been incorporated to address these priorities and gather proposals. In the area of TBI, researchers performed investigations to find a universally-agreed upon concussion grading system, and continued experiments into the effects of penetrating injuries on the brain and experiments on the effects of blasts on the brain. Proposals were solicited in the areas of blast-induced hyper-acceleration upon the generation of TBI and the role of inflammation in spreading TBI damage. Multiple awards relevant to combat casualty care were made including development of a large animal model of penetrating ballistic brain injury and development of metrics to define concussion and grade TBI. In the area of psychological health, researchers performed investigations to diagnose, prevent, and reduce symptoms of PTSD, and understand predictors of violence among workers in military settings.		
Congressional Add: 462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)	19.620	10.000
FY 2015 Accomplishments: FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0602115. Funds supported applied research for military infectious		

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016
diseases, military operational medicine, combat casualty care, radiation health effects and clinical and rehabilitative medicine (Project 372A). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0602115. Funds supported applied research for military infectious diseases, military operational medicine, combat casualty care, radiation health effects and clinical and rehabilitative medicine (Project 372A).		
Congressional Add: 469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0602115. Funds supported research in Military HIV Research (Project 447A) and Combating Antibiotic Resistant Bacteria (Project 246A). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0602115. Funds supported research in Military HIV Research (Project 447A) and Combating Antibiotic Resistant Bacteria (Project 246A).	4.941	1.071
Congressional Add: 469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0602115. Funds supported Air Force research in Advanced Diagnostics and Therapeutics (Project 306B). ***FY 2016 Plans:*** No Funding Programmed.	0.742	0.000
Congressional Adds Subtotals	25.303	16.904

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,

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 200A / *Congressional Special Interests*

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 (S&T) 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
246A: *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	0.000	0.000	3.150	2.860	-	2.860	2.142	1.857	1.949	1.989	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 that simultaneously 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 2015	FY 2016	FY 2017
Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	0.000	3.150	2.860

Description: Initiate 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) initiates partnerships with external collaborators to develop/co-develop new potential antibacterial treatment therapeutics.

FY 2015 Accomplishments:

Established the research program and initiated the assessment of antibacterial programs from companies that have exited the commercial antibacterial drug discovery (direct contact and literature publications) market for potential leads, identified and hired staff, developed desired therapeutic product profile criteria and DoD-focused Target Product Profiles to meet military requirements, and evaluated chemical hits/leads with development potential.

FY 2016 Plans:

Continue applied research to evaluate 2-4 chemical compounds for antibacterial effectiveness in the laboratory and in animals, and complete market analysis of external antibiotic programs to discover small molecules that are in early drug discovery (pre-clinical,1-4 years away from advanced development) that may be expanded or elaborated. Assays are under evaluation to assess potential lead candidates, synthesize key chemical compounds and newly designed lead optimization chemical compounds,

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
begin to establish in vivo (living organism) model standards, and evaluate late stage external programs that could potentially treat military relevant resistant bacteria. Efforts are being made to establish agreements where intellectual property rights are involved. ***FY 2017 Plans:*** Will establish sustainable research efforts designed to evaluate viable small molecule candidate antibacterial agents for planned development for the DoD and Public Health benefit. Will continue expansion of market analysis of external antibiotic programs, compound optimization, and Investigational New Drug-enabling study coordination. Will obtain agreements if intellectual property rights are owned by existing companies or complete partner agreements in order to explore and co-develop new antibiotics leads. Will conduct 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 evaluate one or two viable compounds by FY 2020 that can be transitioned into advanced development.			
Accomplishments/Planned Programs Subtotals	0.000	3.150	2.860

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
306B: *Advanced Diagnostics & Therapeutics Research & Development (AF)*	6.912	2.708	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 2015	FY 2016	FY 2017
Title: Advanced Diagnostics & Therapeutics Research & Development (AF)	2.708	0.000	0.000

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 2015 Accomplishments:

Established genetic marker research data, tissue and specimen repository for future studies. Elucidated the genetic epidemiology of T2D in the MHS population, providing evidence of specific single nucleotide polymorphisms associated with an enhanced risk of future diabetes and prediction of future disease, far in advance of actual disease onset, to reduce disease burden and preserve the military readiness mission, especially in younger adults. Evaluated, optimized and validated sophisticated advanced diagnostic technologies, including automated nucleic acid extraction for complex matrices, DNA next generation sequencing and Real-Time Polymerase Chain Reaction (PCR) technology for RNA and DNA pathogens of both viral and bacterial etiology, advanced molecular biology procedures, bio-informatics, and connectivity and communication endeavors to provide commanders at all levels the information needed to make time-critical disease prevention and control decisions, on the ground where outbreaks occur. Real-Time polymerase chain reaction assays optimized and utilized in sample characterization at the Center for Advanced Molecular Detection clinical repository include Influenza A (H1, H3, H5a and b), Influenza B, Respiratory Syncytial Virus A and B, Human Parainfluenza Virus 1, 2, and 3, Human Metapneumovirus, Rhinovirus, Enteroviruses, Adenovirus (and human Adenovirus subtyping), Human Metapneumovirus, Bocavirus, L. pneumophila, H. influenzae, Streptococcus pyogenes, Streptococcus

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
pneumonia, Bordetella pertussis (I) and parapertussis (II), Chlamydia pneumonia and Mycoplasma pneumonia. Achieved IRB approval for initiation of FY16 protocols. Completed toxicological/functional testing of three organ cell lines. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	2.708	0.000	0.000

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
306C: *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	0.000	0.000	1.728	1.757	-	1.757	1.987	2.025	2.066	2.107	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 2015	FY 2016	FY 2017
Title: Core Adv Diagnostics & Epigenomics Applied Research (AF)	0.000	1.728	1.757

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 2015 Accomplishments:

No funding programmed.

FY 2016 Plans:

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 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. Total FY16 requirements cost is $4.500M; FY16 UFR = $2.772M ***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. Total FY17 requirement is $3.757M; FY17 UFR = $2.000M			
Accomplishments/Planned Programs Subtotals	0.000	1.728	1.757

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.)

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
306D: *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	0.000	0.000	1.728	1.758	-	1.758	1.988	2.026	2.066	2.108	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 2015	FY 2016	FY 2017
Title: Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)	0.000	1.728	1.758

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 2015 Accomplishments:

No funding programmed.

FY 2016 Plans:

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. Develop passive dosimeters to support 24/7 exposure monitoring. Expand toxicological/functional testing of organ cell lines, development of new organ system cell lines and build library of multiple chemical exposure. Continue to develop environmental biosurveillance procedures for monitoring metagenomic drift within field hospitals and forward bases.

FY 2017 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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. Explore capture of assorted biological signatures to characterize health and physiological status.			
Accomplishments/Planned Programs Subtotals	0.000	1.728	1.758

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
372A: *GDF Applied Biomedical Technology*	92.328	32.677	43.579	43.462	-	43.462	49.639	58.724	67.148	68.357	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 (JPCs) in the following areas: 1- Military infectious diseases research is developing protection and treatment products for military relevant infectious diseases. Applied research is conducted in the task areas of bacterial diseases, diagnostics development, and viral diseases. 2- Military operational medicine 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. Applied research is conducted in the task areas of musculoskeletal injury; brain health and performance risk; behavioral health, wellness and resilience; warfighter physical performance; nutrition and weight balance; fatigue countermeasures, psychiatry and clinical psychology disorders; auditory and vestibular performance, injury and protection; blunt, blast and accelerative injury; environmental toxicant exposure; and aircrew health and performance. 3- Combat casualty care research is focused on optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through enroute and facility care. Applied research is conducted in the task areas of hemorrhage, shock, and coagulopathy of trauma; traumatic brain injury (TBI) neurotrauma and brain dysfunction; treatments for extremity trauma, tissue injury, craniomaxillofacial injury, lung injury, and burns; pre-hospital tactical combat casualty care; and enroute care. 4- Radiation health effects applied research supports tasks for the development of radiation medical countermeasures, to include therapeutic candidates for acute radiation once exposure has occurred, and preventative treatment prior to exposure (radioprotectants). 5- Clinical and rehabilitative medicine is developing knowledge and materiel products to reconstruct, rehabilitate, and provide care for injured Service members. Applied research is conducted in the task areas of neuromusculoskeletal rehabilitation, pain management, regenerative medicine, and sensory systems.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: GDF Applied Biomedical Technology	32.677	43.579	43.462
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 2015 Accomplishments: Military infectious diseases research supported multi-year studies in bacterial diseases; progressed in development of four novel therapeutics (e.g., drugs) to mitigate wound infection and biofilm processes, pursued development of tools and practices for the detection/prevention of microbial infections in wounds and/or guide clinical wound management, performed confirmatory laboratory studies and initial animal studies to demonstrate drug potency, and demonstrated biomarker (biological indicator of			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
health outcomes and disease) accuracy and degree of confidence in identifying pathogens. Efforts to maintain subject matter expertise in acute respiratory diseases and diagnostic systems for infectious diseases were continued. Military operational medicine research established animal models to determine risk of performance decrement resulting from repeated low level blast exposure, developed military relevant clinical and functional assessments to determine return to duty after musculoskeletal injury, and developed strategies to model human middle ear dynamics when subjected to impulse noises, which will lead to validating hazardous impulse noise exposure standards. Continued studies aimed at establishing an animal model for dependency and withdrawal associated with prescription drugs and substance abuse. Continued research to understand how to support family resilience and behavioral health during deployment and reintegration to inform intervention development. Continued studies focused on selecting candidate biomarkers for objective Posttraumatic Stress Disorder (PTSD) screening, pilot research evaluating novel PTSD intervention strategies, and adaptations of existing evidence-based psychotherapies for PTSD treatment. Developed a reporting system for adverse events associated with dietary supplement use, and developed computational models that can predict bone and muscle health status. Established risk factors for heat injury susceptibility, studied select candidate biomarkers for inhalation exposure to toxic substances, and conducted dehydration studies to select stress biomarkers of hydration status. These research efforts supported the Precision Medicine Initiative. Combat casualty care hemorrhage research made progress toward supporting studies assessing the effectiveness of Valproic Acid, a FDA-approved anti-seizure drug, and ethinyl estradiol to increase survival of severe hemorrhage. Established effects of modulating the inflammatory response associated with hemorrhagic shock and trauma, and examined specific mechanisms that may be involved in coagulopathy of trauma. TBI neurotrauma research made progress in developing TBI biomarkers and screening tools. Treatments for extremity trauma addressed burn, acute lung injury, and enhanced healing of complex injuries of the face, extremities, groin and pelvis. Pre-hospital tactical combat research included resuscitative interventions through seamless critical care. The enroute care task made significant advances to understand and improve field management and safe air transport of patients with head and spine injuries. Radiation health effects research pursued 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 address research data gaps and to characterize several compounds with potential to mitigate or prevent Acute Radiation Syndrome (ARS) resulting from lethal doses of radiation. The research aimed to determine mechanisms of action, effectiveness, and safety in animal models in the development of therapeutics for ARS hematopoietic (bone marrow) sub-syndrome. Clinical and rehabilitative medicine research conducted applied research in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and/or sensory (hearing and sight) system traumatic injury. The neuromusculoskeletal injury portfolio examined the impact of biopsychosocial effects on rehabilitation, improved the current technology available for			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
residual limb-device interface, and developed objective metrics for device prescription and training. In pain management, research was conducted that studied enhanced chronic pain management using receptor antagonists (agents that block biochemical responses). Regenerative medicine research studied novel tissue-engineered nerve grafts for currently unrepairable nerve injury, and treatment for re-innervated (restored nerve function) muscle. Sensory systems research studied pre-clinical testing of sustained release drugs to prevent blinding complications following eye injury, and developed therapeutic drugs for hearing restoration after noise induced hearing loss. ***FY 2016 Plans:*** Military infectious diseases research supports multi-year studies in bacterial diseases, and continues the development efforts of four antibacterial projects and two projects for the detection of microbial infections in wounds. Studies are 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 are being evaluated for further development. Continue efforts to maintain subject matter expertise in acute respiratory diseases. These studies are in alignment with the National Strategy for Combating Antibiotic Resistance. Military operational medicine research is validating repeated low level blast injury animal models compared to occupational blast exposures, developing computational models of the nonlinear middle ear function to establish hearing injury criteria, developing improved clinical strategies to determine safe return to duty after severe musculoskeletal injury, and characterizing the effects of hypoxia (oxygen deficiency) and fatigue on aircrew performance in rotary and fixed wing aircraft. Conducting applied research to develop strategies for building Service member and family resilience and to support successful reintegration following deployment. Continuing to establish associations between military service, deployment, risk and protective factors, and psychological and physiological health problems to inform development of policies and guidelines. Continuing 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. Developing interventions for sustainable weight loss in military families, and continuing the development of computational models that can predict bone and muscle health status. Performing studies of risk factors for heat injury susceptibility and develop a non-invasive tool for diagnosing pulmonary disease. C Conducting studies for novel mitigation and treatment strategies and biomarker detection to optimize physiological performance and protect against multi-environmental injury. Refining biomarkers of environmental exposure to toxic substances inhaled or ingested that will be used for establishing the probability of adverse health risk outcomes. Conducting studies to define metrics for optimized performance in extreme environmental conditions.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Combat casualty care hemorrhage research continues to search for new diagnostic tools and the development of treatments for abnormal hemorrhage following injury. Work focuses primarily on inflammatory modulation (determining the efficacy of complement inhibitors in swine) and coagulopathy of trauma (computational and mathematical modeling of coagulopathy of trauma). Neurotrauma research is further developing and investigating TBI biomarkers and screening tools for far-forward medical evaluation of warriors. Forward Surgical and Intensive Critical Care is studying 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 address burn, acute lung injury, and enhanced healing of complex injuries of the face, extremities, groin and pelvis. Tissue injury research is also addressing wound stabilization in the prolonged field care scenario and will continue to specifically address the need for a maxillofacial stabilization dressing. The enroute care research is studying 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 is continuing strategies for protection, mitigation, and treatment of radiation-induced tissue injury due to high doses of radiation exposure. Conduct 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 address bone marrow (hematopoietic) and gastrointestinal effects. Pulmonary effects of radiation exposure are also being examined. Based on research accomplishments, compounds are being evaluated as potential candidates for transition toward advanced development. Additional efforts are evaluating 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 is pursuing down-selection of candidate products for transition to technology development in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and/or sensory (hearing, sight, and balance) system traumatic injury. Conducting applied research in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation after Service-related injuries. Studying the effectiveness of leading solutions to alleviate acute and chronic battlefield pain, investigating solutions to replace or regenerate human cells, tissues, or organs to restore or establish normal tissue function, and conducting applied research to identify therapeutic targets to restore visual, auditory, and vestibular function following traumatic injury. ***FY 2017 Plans:*** Military infectious diseases research will support multi-year studies initiated in FY 2014 and FY 2015 in bacterial diseases research, and will down-select promising efforts for further development. Program announcements in wound infection will be released to address critical research focus areas such as the ability to predict infection and better treatment options for infections			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
with multi-drug resistant organisms. Will continue efforts to maintain subject matter expertise in acute respiratory diseases. These studies will support the National Strategy for Combating Antibiotic Resistance. Military operational medicine research will collect experimental data to validate whole-body computational models for the direct and indirect mechanism of blast brain injury and quantify the biomechanical brain-tissue response, determine optimal temporal spacing of repeated blast events to prevent cumulative effects, collect impulse noise experimental data to validate computational models of the inner ear to validate injury criteria, and will develop comprehensive aircrew performance risk models of fatigue and hypoxia (oxygen deficiency). Will continue to monitor the patterns of dietary supplement use in the Armed Forces and determine demographic and lifestyle factors associated with dietary supplement and caffeine use along with coincident motivating factors. Will assess the psychosocial and physiological factors affecting overuse injury susceptibility and career success of female Warriors. Will conduct applied research to develop prevention skills training and interventions to prevent suicide behaviors. Will complete studies that will inform opioid abuse risk reduction strategies. Will deliver prototypes for Service member and family resilience building interventions. Will continue 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. Will continue to refine 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. Will 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. Work focuses primarily on modulating inflammation (determining the efficacy of complement inhibitors in swine) and coagulopathy of trauma (computational and mathematical modeling of coagulopathy of trauma). Will begin to focus on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Inflammatory modulation and other work will begin to focus on the time period from 4 to 72 hours post-injury (related to prolonged field care scenarios). Neurotrauma research will further develop identified TBI biomarkers and screening tools for far-forward medical evaluation of warriors; develop clinical tools/treatments to minimize the progression of TBI at point of injury; and provide capabilities for the treatment, management and monitoring of moderate and severe head injuries in accordance with Advanced Trauma Life Support (ATLS) protocols in a far forward environment. 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 for burn, acute lung injury, and complex injuries to include maxillofacial injury. Forward Surgical and Intensive Critical Care will study the effectiveness of acute lifesaving interventions and how to improve survival for those in need of critical care on the battlefield and in acute stages of injury and for those requiring prolonged times until reaching definitive care in the pre-hospital/hospital setting. Enroute care research will study clinically-relevant testing standards for monitors in the transport environment and will develop new non-invasive monitoring technologies.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Radiation health effects research will conduct non-clinical research to identify ARS therapeutic candidates for acute radiation exposure and develop data to support preparation of technical data package requirements, as detailed in the Code of Federal Regulations, Chapter 21, Part 312. Research will also focus on evaluating candidate radioprotectants (prophylaxes) to determine their feasibility and practicality as candidate solutions to military needs. 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 guide 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 evaluate 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.			
Accomplishments/Planned Programs Subtotals	32.677	43.579	43.462

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.

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
447A: *Military HIV Research Program (Army)*	8.410	6.549	8.066	7.438	-	7.438	7.794	9.022	9.654	9.847	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 US Army Medical Research and Materiel Command (USAMRMC) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). 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 2015	FY 2016	FY 2017
Title: Military HIV Research Program	6.549	8.066	7.438
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 2015 Accomplishments: Completed production of additional vaccine candidates for various world-wide subtypes. Developed improved methods to evaluate immune responses to selected HIV vaccine candidates in non-human primates. Analyzed host genetic factors related to HIV acquisition and disease progression in acute HIV infection to inform vaccine development. Completed down-selection of best candidates for use in Phase 1 safety studies in human volunteers.			
FY 2016 Plans: Continue to produce additional vaccine candidates for various world-wide subtypes. Characterize these new sub-types and evaluate their capability to induce protective immune responses in non-human primates. Down-select one or more vaccine candidates for use in safety studies in human volunteers.			
FY 2017 Plans: Will finalize production and optimization of three new vaccine candidates from an East African region. Will characterize these new sub-types and evaluate their capability to induce protective immune responses in non-human primates by using novel delivery			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
systems. Will down-select 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). Will also design 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 continue to develop new clinical trial sites in Mozambique that will allow scientists the opportunity to test future vaccine candidates against the predominant HIV subtype (C) circulating in this part of the world.			
Accomplishments/Planned Programs Subtotals	6.549	8.066	7.438

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 (IIPT) and in-process reviews (IPR).

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0602787DHA / *Medical Technology (AFRRI)*							
COST ($ in Millions)	**Prior Years**	**FY 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	5.857	1.145	1.222	1.242	-	1.242	1.331	1.356	1.383	1.411	Continuing	Continuing
020: *CSI - Congressional Special Interests*	0.000	0.124	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
241A: *Biodosimetry (USUHS)*	1.195	0.208	0.249	0.254	-	0.254	0.272	0.277	0.283	0.289	Continuing	Continuing
241B: *Internal Contamination (USUHS)*	0.621	0.109	0.131	0.133	-	0.133	0.143	0.146	0.149	0.152	Continuing	Continuing
241C: *Radiation Countermeasures (USUHS)*	4.041	0.704	0.842	0.855	-	0.855	0.916	0.933	0.951	0.970	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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	1.117	1.222	1.242	-	1.242
Current President's Budget	1.145	1.222	1.242	-	1.242
Total Adjustments	0.028	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.124	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.096	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Project: 020: *CSI - Congressional Special Interests*		
Congressional Add: *472A – Program Increase: Restore Core Research Funding Reduction (USUHS)*	0.124	0.000

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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 2015	FY 2016
Congressional Add Subtotals for Project: 020	0.124	0.000
Congressional Add Totals for all Projects	0.124	0.000

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0602787-Medical Technology (AFRRI) (-$0.096 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$0.096 million).

FY 2015: Restore core research funding to the DHP RDT&E, PE 0602787-Medical Technology (AFRRI) (+$0.124 million).

FY 2016: No Change.

FY 2017: No Change.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
020: *CSI - Congressional Special Interests*	0.000	0.124	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 2015	FY 2016
Congressional Add: 472A – Program Increase: Restore Core Research Funding Reduction (USUHS)	0.124	0.000
FY 2015 Accomplishments: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology (AFRRI) Program Element (PE) - 0602787.		
FY 2016 Plans: No Funding Programmed.		
Congressional Adds Subtotals	0.124	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
241A: *Biodosimetry (USUHS)*	1.195	0.208	0.249	0.254	-	0.254	0.272	0.277	0.283	0.289	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 2015	FY 2016	FY 2017
Title: Biodosimetry (USUHS)	0.208	0.249	0.254
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.			
FY 2015 Accomplishments: - Sustained studies evaluating new radiation-responsive biomarkers in animal models for early-phase and organ-specific bio indicators. - Reported on development of circulating pro-inflammatory factor IL-18 as novel radiation biomarker in mice, mini pigs and nonhuman primates. - Reported mechanisms of microRNA-30 as apoptosis inducer released in mouse serum in radiation dose-dependent manner, useful for radiation biomarker. - Characterized dosimetry and radio response for use of multiple parameter radiation biomarkers in a murine partial-body exposure model. - Sustained efforts to provide 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). - Began pilot study using blood samples from mouse and NHP total-body irradiation models to permit testing of measurement of novel tissue- and organ-specific biomarkers in peripheral blood using commercially available antibodies and assays developed at AFRRI.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
- Began to analyze hematology and blood serum chemistry data collected in NHP dose-response study with limited supportive care and in high-dose study with full supportive care (G-CSF, antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs. - Began to analyze results of necropsies performed on NHPs (limited and full supportive care) to determine radiation dose-dependent damage to different organs/tissues and correlate those results with levels of tissue/organ-specific protein biomarkers. - Began to compare results/data from NHP dose-response TBI (photon/low-LET) studies with data collected from radiation accident victims and radiation therapy patients - Completed pilot studies to establish 3-D primary mouse intestinal epithelial cell (IEC) organoid culture model and characterized radiation effects on histological and proteomic profile using LC-MS/MS. - Continued studies to evaluate effects of low dose radiation on hematology and leukemia markers and identified specific changes in epigenetic markers. - Initiated study to determine whether epigenetic markers i.e., histone methylation and acetylation, could discriminate between low dose single and low dose repeated exposures. - Initiated study to assess whether epigenetic markers i.e., DNA or histone methylation, or miRNA levels, could discriminate differences in dose rate.			
FY 2016 Plans: - 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. - Continue studies evaluating new radiation-responsive biomarkers in animal models for early-phase and organ-specific damage. - Continue pilot study using blood samples from mouse and NHP total-body irradiation models to permit testing of measurement of novel tissue- and organ-specific biomarkers in peripheral blood using commercially available antibodies and assays developed at AFRRI. - Complete analysis of hematology and blood serum chemistry data collected in NHP dose-response study with limited supportive care and in high-dose study with full supportive care (G-CSF, antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs. - Complete analysis of results of necropsies performed on NHPs (limited and full supportive care) to determine radiation dose-dependent damage to different organs/tissues and correlate those results with levels of tissue/organ-specific protein biomarkers. - Continue comparing results from NHP dose-response TBI (photon/low LET) studies with data collected from radiation accident victims and radiation therapy patients. - Assess whether hematology and leukemia markers during leukemogenesis can be differentially expressed at early and late phases of carcinogenesis. - Determine whether epigenetic changes can be used to discriminate differences in dose rate at low doses.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
- Develop IL-18 and IL-18 binding protein (IL-18BP) as dual biomarkers for assessment of radiation dose, severity and lethality in mice after total body radiation exposure. - Evaluate correlations between level of radiation biomarkers and survival rate in individual mice after radiation. ***FY 2017 Plans:*** - Report on use of multiple parameter biodosimetry for radiation dose assessment using murine partial-body exposure model. Initiate effects to measure chromosomal aberrations in mouse radiation model in support of dose assessment using multiple parameter biodosimetry. - Establish partial-body animal radiation models (mouse and NHP) using animals involving low-LET 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 approach following mixed-field (photon and neutron, high-LET) in addition to one already established and evaluated for a pure photon (60Co γ-rays, low-LET) exposure. - Test murine model system to assess specific low dose epigenetic markers. - Establish in vitro and in vivo parameters for AFRRI low level radiation facility for multiple delayed radiation organ effects. - Evaluate effects and mechanisms of proinflammatory cytokine IL-18 and IL-18BP on radiation-induced cell damage and apoptosis pathways. - Develop circulating miRNAs profile in γ-irradiated mouse serum using miRNA microarray and quantitative reverse transcription (RT)-real-time-polymerase chain reaction (PCR). - Evaluate threshold doses of radiation-induced lymphocyte damage.			
Accomplishments/Planned Programs Subtotals	0.208	0.249	0.254

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY 2015

- Begin analyses of blood samples from mouse and NHP total-body irradiation models to identify novel tissue- and organ-specific biomarkers.
- Begin analysis of blood chemistry data collected in NHP dose-response study with limited supportive care and in high-dose study with full supportive care (G-CSF, antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241A / *Biodosimetry (USUHS)*

- Begin analysis of results of necropsies performed on NHPs (limited and full supportive care) to determine radiation dose-dependent damage to different organs/tissues and correlate those results with levels of tissue/organ-specific protein biomarkers.
- Provide 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) and obtain necessary FDA approval.
- Prepare preliminary report for FDA on combined utility of hematological and protein biomarkers for biodosimetry applications in two FDA-required animal models.
- Begin to compare results/data from the NHP dose-response TBI (photon/low-LET) studies with data collected from radiation accident victims and radiation therapy patients.
- Report on dosimetry and radioresponse for use of multiple parameter radiation biomarkers in a murine partial-body exposure model.
- Identify proteomic markers from irradiated organoid cultures for validation by enzyme linked immunosorbent assay.
- Initiate studies to evaluate radiation-induced chromosomal damage in murine radiation model.
- Measure epigenetic markers in early, mid, and late carcinogenesis samples after low dose radiation.
- Identify differences in cell growth rate responses to low and high dose rate radiation in cell samples.
- Measure and compare epigenetic markers in low and high dose rate cell samples at single low dose.

By FY 2016
- Evaluate new early-phase and organ-specific damage radiation-responsive biomarkers in animal models.
- Compare/correlate hematology, blood serum chemistry, protein biomarkers and necropsy results in NHP dose-response study to evaluate radiation damage to specific organs.
- Compare results/data from NHP dose-response TBI (photon/low LET) studies with data collected from radiation accident victims and radiation therapy patients.
- Continue to refine combination of radiation biomarkers in blood with best balance of discrimination, sensitivity and specificity.
- Evaluate predictive radiation-responsive biomarkers in animal models for ARS outcome.
- Continue partial-body exposure study to characterize organ specific injury biomarkers using abdomen exposures of mice.
- Identify specific gene pathways that differ in early, mid, and late carcinogenesis samples after low dose radiation.
- Characterize dose rate effects on cell growth to identify gene pathway differences between low and high dose.
- Evaluate role of miR30 on regulation of radiation-induced apoptosis and apoptotic protector Mcl-1 activation in cells and in mitochondria.

By FY 2017
- Establish partial-body animal radiation models (mouse and NHP) using animals involving low-LET 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 approach following mixed-field (photon and neutron, high-LET) in addition to one already established and evaluated for a pure photon (60Co γ-rays, low-LET) exposure.
- Report on use of multiple parameter biodosimetry to characterize partial-body exposures using murine model.
- Measure leukemia development in vivo after chronic low dose radiation, and identify specific genes silenced in early, mid, and late leukemogenesis
- Identify network of miRNAs and their targeting mRNAs in radiation-induced apoptotic signal pathways.
- Evaluate mechanisms of radiation-induced lymphocyte damage.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241A / *Biodosimetry (USUHS)*

- Develop biomarkers which can identify “treatment-point” after radiation injury.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
241B: *Internal Contamination (USUHS)*	0.621	0.109	0.131	0.133	-	0.133	0.143	0.146	0.149	0.152	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 2015	FY 2016	FY 2017
Title: Internal Contamination (USUHS)	0.109	0.131	0.133

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 2015 Accomplishments:
- Initiated feasibility study to determine if non-radioactive metals can substitute as template molecules for high-specific activity radionuclides in synthesis of molecularly imprinted polymers.
- Identified specific epigenetic changes associated with depleted uranium damage in vivo.
- Measured genes associated with chromatin regulation in depleted uranium leukemia in vivo.

FY 2016 Plans:
- Evaluate kidney gene pathway changes induced by depleted uranium in vivo.
- Design feasibility study to determine if non-radioactive metals can substitute as template molecules for high-specific activity radionuclides in the synthesis of molecularly imprinted polymers.

FY 2017 Plans:
- Design feasibility study to assess chelating potential of molecularly imprinted polymers linked to magnetic nanoparticles.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
- Initiate study to determine if depleted uranium and low dose radiation induced changes in chromatin remodeling can be reversed by countermeasures.			
Accomplishments/Planned Programs Subtotals	0.109	0.131	0.133

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY15
- Initiate feasibility study to determine if non-radioactive metals can substitute as template molecules for high-specific activity radionuclides in synthesis of molecularly imprinted polymers.
- Complete in vivo study on the mechanism of depleted uranium-induced leukemia.

By FY 16
- Conclude feasibility assessment studies on possibility of using non-radioactive templates for the synthesis of molecularly imprinted polymers designed to bind radioactive metals.
- Continue study to assess novel countermeasure to low dose radiation that targeted specific chromatin remodeling.

By FY 2017
- Initiate study to assess applicability of nanoparticle-linked molecularly imprinted polymers for radionuclide de-corporation.
- Measure specific chromatin changes that are associated with low dose radiation or depleted uranium exposure in vivo.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
241C: *Radiation Countermeasures (USUHS)*	4.041	0.704	0.842	0.855	-	0.855	0.916	0.933	0.951	0.970	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 2015	FY 2016	FY 2017
Title: Radiation Countermeasures (USUHS)	0.704	0.842	0.855

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 2015 Accomplishments:
- Completed strain comparison studies to establish the efficacy of 3 doses of filgrastim in mice exposed to LD70/30 dose of Co-60 radiation.
- Completed strain comparison studies to establish the efficacy of 3 doses of filgrastim in accelerated recovery from radiation-induced pancytopenia in mice exposed to sub-lethal dose of Co-60 radiation.
- Identified micro-RNAs involved in the GT3 mediated recovery from radiation-induced damage in spleen.
- Studied efficacy of TPOm administered subcutaneously 24 h before exposure to radiation.
- Performed comparative study of GT3, DT3 and DG70 administered subcutaneously. Formulations supplied by American River Nutrition.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
- Determine efficacy of CDX-301 in gastrointestinal recovery after radiation exposure. - Demonstrated efficacy of TPOm in hematopoietic recovery after radiation exposure. - Completed micro-RNA profiles in serum and kidney of mice exposed to radiation followed by hemorrhage. - Determined ionizing radiation weakly activates production of inflammatory cytokines and chemokines in macrophage cell lines and ex vivo bone marrow derived macrophages. - Combined exposure to ionizing radiation and virus infection increased inflammatory response in macrophages above single pathophysiological exposures. - Discovered that, unexpectedly, inflammatory response in macrophages controlled primarily by Mitogen Activated Kinases (MAPK), not the expected Nuclear Factor kappa B (NF-kB) gene transcription factors. - Determined phenylbutyrate induced suppression of x-ray induced neoplastic transformation of bronchial tissue. - Measured DNA methylation changes in neoplastic bronchial cells that demonstrated radiation quality effect. - Discovered use of MAPK inhibitors can decrease radiation induced cytokine production by macrophages when added pre- and post- exposure, and for selected exposure/treatment combinations up to 72 hours. - Established that cells from multiple cell linages with stable gene constructs that report gene promoter activity can be used to evaluate effects of ionizing radiation, infectious disease agent agonists and effects of response modulators. - Developed two different types of nanoparticles sensitive to oxidative stress and activation by UV light, respectively. - Discovered nanoparticle encapsulated anti-oxidants that modulate macrophage response to infectious disease agent agonists are equally or more effective than when modulator is in free solution. - Screened 10 radiation countermeasure candidates administered before irradiation to mice, to parallel externally funded program (NIAID) that screened countermeasures given after irradiation. (Civilian agencies do not fund pre-irradiation countermeasures.) - Established coculture model comprising human bone marrow endothelial cells (EC) (hematopoietic microenvironment cells) and human hematopoietic stem and progenitor cells (HSPC). - Showed EC and radiation affect expression of differentiation markers on HSPC: HSPC remain undifferentiated after radiation, and EC accentuate this process. - Discovered subpopulations of HSPC affected differently by EC and radiation. - Discovered radiation-responsive genes in EC, some of which are also modulated by the presence of HSPC. These genes include DNA repair genes and Angiopoietin-1 (Ang-1). - Discovered Ang-1 modulated interactions between EC and HSPC. - Initiated informatics analysis of gene array data from irradiated, co-cultured EC and HSPC. - Reported effects and mechanisms of delta-tocotrienol on radioprotection are through suppression of radiation-induced microRNA-30, protecting mice and human CD34+ cells from radiation injury. - Studied radioprotective efficacy of Ex-RAD in two different strains of mice (CD2F1 and C57BL/6) to demonstrate that countermeasure effective across various mice strains.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
- Evaluated efficacy biomarkers of Ex-RAD using in-vitro models (different cell lines) and several target proteins of various pathways. - Initiated study of efficacy biomarkers for Ex-RAD in mouse model. ***FY 2016 Plans:*** - Perform dose and time optimization and DRF of TPOm. - Determine efficacy of DG70 and nano-GT3 administered orally. - Determine role of micro-RNA in regulating recovery of hematopoietic system by CDX-301 after radiation injury. - Determine effects of citrulline in vitro on human hematopoietic progenitors and other cell lines. - Evaluate mTOR-AKT signaling and MAPK signaling in bone marrow cells 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 cytokines associated with ileal recovery after radiation CI. - Determine which specific MAPK pathway intermediates activated in macrophages by ionizing radiation and virus exposure singly and in combination. - Determine effects of ionizing radiation on production of Type I interferon by macrophages. - Determine how reporter cells containing more than one transcription factor can be utilized to gain simultaneous information from dual reporter system. - Develop new interferon detection assay utilizing reporter gene cell lines. - Complete development of oxidation-sensitive drug delivery system tuned to degrade at a rate corresponding to level of oxidants present within microenvironment of the cell. - Complete development multi-photon-responsive nanocarrier designed to respond to UV light, near infrared (NIR) light and ionizing radiation (IR). - Improve low dose risk assessment knowledge base by determining whether chronic or repeated low dose exposure in murine model induces leukemia in comparison to high dose radiation exposure. - Screen 10 radiation countermeasure candidates administered before irradiation to mice, to parallel externally funded program (NIAID) that screens countermeasures given after irradiation. (Civilian agencies do not fund pre-irradiation countermeasures.) - Screen 3 radiation countermeasure candidates originating from AFRRI in mouse survival assay. - Optimize dose and administration timing of promising new radiation countermeasures in mice. - Complete informatics analysis of irradiated, co-cultured EC and HSPC. - Determine effects of ionizing radiation on mitochondrial remodeling and mitophagy. - Compare radioprotective and mitigative effects of γ-tocotrienol (GT3), δ-tocotrienol (DT3) and DeltaGold® (DG) on mouse hematopoietic system and human hematopoietic progenitor cells. - Continue study of efficacy biomarkers for Ex-RAD in mouse model.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
- Initiate study of efficacy biomarkers for Ex-RAD in nonhuman primate (NHP) model using biosample sharing arrangement with an extramural project.			
FY 2017 Plans: - Determine protective and mitigative effects of citrulline in vitro on human hematopoietic progenitors and other cell lines exposed to radiation. - Determine whether oral citrulline before and after radiation enhances survival in mice. - Determine effects of citrulline on GI injury in irradiated mice. - 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 hypoxia. - Evaluate whether ghrelin therapy reduces tissue injury and improves tissue recovery. - Determine whether modulation of radiation-virus induced inflammatory response is best inhibited by use of broad MAPK inhibitors or ones selective for specific targeted pathway intermediates. - Determine MAPK and IRF pathway in human ex vivo macrophages and response during combined exposure to ionizing radiation and FLUA. - Validate pathways resulting in activation of the reporter genes in stably transfected cell lines. - Determine effects of anti-oxidants and other response modifiers of radiation injury, infectious disease inflammatory stimulation and combined injury which result in activation of stable transcription factor reporters. - Measure incidence of leukemia development in vivo after chronic low dose rate radiation or repeated exposure to high dose rate radiation. - Screen 10 radiation countermeasure candidates administered before irradiation to mice, to parallel externally funded program (NIAID) that screens countermeasures given after irradiation. (Civilian agencies do not fund pre-irradiation countermeasures.) - Screen 3 radiation countermeasure candidates originating from AFRRI in mouse survival assay. - Optimize dose and administration timing of promising new radiation countermeasures in mice. - Initiate studies on role of radiation-induced mitochondrial DNA (mtDNA) damage and mitochondrial dysfunction in acute radiation syndrome. - Compare radioprotective effects of DG/DT3/GT3 on mouse gastrointestinal (GI) tract. - Determine and compare mechanisms by which DG/DT3/GT3 mediate survival signaling after radiation. - Evaluate mechanisms of radiation-induced mitochondria DNA damage and apoptosis pathways. - Evaluate effects of DG/DT3/GT3 on protection and/or mitigation of radiation-induced mitochondrial DNA damage. - Study radioprotective efficacy of two drug combination acting through two different mechanisms of action: gamma-tocotrienol (GT3) and amifostine. - Continue study of efficacy biomarkers for Ex-RAD in NHP model.			
Accomplishments/Planned Programs Subtotals	0.704	0.842	0.855

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602787DHA / *Medical Technology (AFRRI)*	**Project (Number/Name)** 241C / *Radiation Countermeasures (USUHS)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY 2015

- Complete toxicity and survival efficacy of DG70, DT3 and GT3 administered subcutaneously.
- Complete preliminary survival efficacy of TPOm.
- Complete study to demonstrate that CDX-301 protects gastrointestinal system in mice exposed to lethal dose of radiation.
- Screen 10 radiation countermeasure candidates administered before irradiation to mice, to parallel externally funded program (NIAID) that screens countermeasures given after irradiation. (Civilian agencies do not fund pre-irradiation countermeasures.)
- Optimize dose and administration timing of promising new radiation countermeasures in mice.
- Establish coculture model comprising human bone marrow endothelial cells (EC) (hematopoietic microenvironment cells) and human hematopoietic stem and progenitor cells (HSPC).
- Show EC and radiation affect expression of differentiation markers on HSPC.
- Assess whether there are subpopulations of HSPC affected differently by EC and radiation.
- Assess radiation-responsive genes in EC; determine whether some are modulated by presence of HSPC.
- Analyze role of Ang-1 in interactions between EC and HSPC.
- Initiate informatics analysis of gene array data from irradiated, co-cultured EC and HSPC.
- Identify additional biomarkers which can be used as efficacy biomarkers for radiation countermeasures.

By FY 2016

- Complete time and dose optimization and DRF of TPOm.
- Complete study to demonstrate the efficacy of TPOm in hematopoietic recovery.
- Complete toxicity and survival efficacy of DG70 and nano-GT3 administered orally.
- Analyze signaling pathways in mouse organs after exposure to radiation using qRT-PCR, Western blots and informatics.
- Complete evaluation of mTOR-AKT signaling and MAPK signaling in bone marrow cells 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 the key cytokine(s) that is/are associated with ileal recovery after CI.
- Complete identification and kinetics of MAPK signaling pathway molecules which are activated by ionizing radiation-virus combined injury.
- Complete evaluation of gene activation reporter cells as new and novel Type I interferon assay.
- Complete identification of MAPK intermediates activated by ionizing radiation and combined injury.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 ionizing radiation and combined radiation-microbial agonist exposures.
- Screen 10 radiation countermeasure candidates administered before irradiation to mice, to parallel externally funded program (NIAID) that screens countermeasures given after irradiation. (Civilian agencies do not fund pre-irradiation countermeasures.)
- Screen 3 radiation countermeasure candidates originating from AFRRI in mouse survival assay.
- Optimize dose and administration timing of promising new radiation countermeasures in mice.
- Complete informatics analysis of irradiated, co-cultured EC and HSPC.
- Determine effects of ionizing radiation on mitochondrial remodeling and mitophagy.
- Continuation of biomarker identification for radiation countermeasure efficacy.
- Identify additional biomarkers for radiation injury.

By FY 2017
- Analyze ERK/MAPK signaling and mRNA responses in endothelial cells to radiation.
- Analyze miRNA and mRNA responses in mice to radiation and radiation countermeasure CDX-301.
- Correlate mTOR-AKT and MAPK signaling network and ATP production after radiation-hemorrhage CI.
- 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 hypoxia.
- Determine whether ghrelin therapy reduces tissue injury and improves tissue recovery.
- Complete assessment of timing and duration of response to MAPK pathway inhibitors to alter inflammatory macrophages exposed to radiation.
- Complete assessment of ex vivo human macrophage response to ionizing radiation, viral infection and combined injury.
- Complete assessment of transcription factor reporter cells to test biological response modulators of gene activation induced by ionizing radiation, microbial agonists and combined exposures.
- Measure incidence of leukemia development in vivo after chronic low dose rate radiation or repeated exposure to high dose rate radiation.
- Screen 10 radiation countermeasure candidates administered before irradiation to mice, to parallel externally funded program (NIAID) that screens countermeasures given after irradiation. (Civilian agencies do not fund pre-irradiation countermeasures.)
- Screen 3 radiation countermeasure candidates originating from AFRRI in mouse survival assay.
- Optimize dose and administration timing of promising new radiation countermeasures in mice.
- Initiate studies on role of radiation-induced mitochondrial DNA (mtDNA) damage and mitochondrial dysfunction in acute radiation syndrome.
- Transcriptomic analysis after irradiation and treatment with various radiation countermeasures.

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
Total Program Element	1.273	0.286	0.305	0.310	-	0.310	0.332	0.338	0.345	0.352	Continuing	Continuing
030A: *CSI - Congressional Special Interests*	0.000	0.031	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
242A: *Biodosimetry (USUHS)*	0.765	0.153	0.183	0.186	-	0.186	0.199	0.202	0.206	0.210	Continuing	Continuing
242B: *Radiation Countermeasures (USUHS)*	0.508	0.102	0.122	0.124	-	0.124	0.133	0.136	0.139	0.142	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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	0.279	0.305	0.310	-	0.310
Current President's Budget	0.286	0.305	0.310	-	0.310
Total Adjustments	0.007	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.031	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.024	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Project: 030A: *CSI - Congressional Special Interests*		
Congressional Add: *473A – Program Increase: Restore Core Research Funding Reduction (USUHS)*	0.031	0.000

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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 2015	FY 2016
Congressional Add Subtotals for Project: 030A	0.031	0.000
Congressional Add Totals for all Projects	0.031	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.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
030A: *CSI - Congressional Special Interests*	0.000	0.031	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 2015	FY 2016
Congressional Add: 473A – Program Increase: Restore Core Research Funding Reduction (USUHS)	0.031	0.000
FY 2015 Accomplishments: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0603002. Funds supported University research in biodosimetry and radiation countermeasures (Projects 242A,B). ***FY 2016 Plans:*** No Funding Programmed.		
Congressional Adds Subtotals	0.031	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
242A: *Biodosimetry (USUHS)*	0.765	0.153	0.183	0.186	-	0.186	0.199	0.202	0.206	0.210	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 2015	FY 2016	FY 2017
Title: Biodosimetry (USUHS)	0.153	0.183	0.186
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 2015 Accomplishments: - Contributed to the further evaluation of discovered new radiation-responsive biomarkers in higher order animal and human models for diagnostic bio-dosimetry applications. - Completed NHP-specific ARS category score system based on multiple bio-dosimetric endpoints (i.e., clinical signs, peripheral blood cell counts, and radiation-responsive protein expression profile). - Began pilot study using samples from the NHP total-body irradiation model, to permit testing of measurement of novel organ-specific biomarkers in isolated peripheral blood using commercially available antibodies and assays developed at AFRRI. - Created multiparametric (hematological and selected protein biomarkers) full dose-response algorithm dose assessment study in NHP total-body irradiation model.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
- Contributed in preparation of summary report for FDA use on diagnostic utility of combined hematological and proteomic approach for triage biodosimetry applications based on combination of hematological and proteomic biomarkers results using minipigs and nonhuman primate models. - Sustained efforts to provide 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) and obtain necessary FDA approval. - Continued to create a human baseline data base for evaluated biomarkers for use in human radiation accident cases. - Began comparing results from NHP dose-response TBI (photon/low-LET) studies with data collected from radiation accident victims and radiation therapy patients. - Enhanced cytogenetic biodosimetry protocols for radiation dose assessment by expanding database of baseline chromosome aberration frequency, adopting use of karyotyping software utility to screen for potential clonal aberrations, extending dose-response calibration curve to low doses (i.e., 10cGy), and successfully participating in several blind exercises using the lymphocyte metaphase spread dicentric chromosome aberration (DCA) assay. - Initiated studies to establish premature chromosome condensation (PCC) assay to permit assessment of partial-body exposures at high doses (i.e., 20-30 Gy). - Used multiple blood cell types (i.e., lymphocyte, neutrophils, and platelets) in development of algorithm for radiation dose assessment for extended times after radiation exposure. - Transitioned Windows-based software application (i.e., First-responder Radiological Assessment Triage or FRAT) for use on mobile Android cell phone. - Developed radiation risk 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. - Determined feasibility of discerning early (≤7 days) and/or late (>7 days) radiation-responsive urinary metabolite and protein biomarkers in nonhuman primates for the development of a radiation risk categorization (RRIC) algorithm for TBI doses between 1 to 8 Gy.			
FY 2016 Plans: - Sustain efforts to establish clinical laboratory quality control and assurance system for radiation dose assessment by cytogenetic biodosimetry. Expand upon baseline measurements for DCA and PCC assays, continue scoring to establish a robust dose-response calibration curve, and participate in exercises. - Continue to provide improved radiation diagnostic tools for use by DOD end-users. Extend transition of mobile FRAT software application for use on iPhone OS devices. Sustain AFRRI's Biodosimetry Tools website for access to diagnostic worksheets and software applications. - Contribute to further evaluation of discovered new radiation-responsive biomarkers in higher order animal and human models for diagnostic biodosimetry applications.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
- Continue evaluating new predictive radiation-responsive biomarkers in NHP models for ARS outcome and their applicability in humans. - Complete NHP-specific ARS category score system based on multiple biodosimetric endpoints (i.e., clinical signs, peripheral blood cell counts and chemistry, pathology reports, and radiation-responsive protein expression profile). - Sustain efforts to provide 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) and obtain necessary FDA approval. - Sustain efforts in comparing results/data from the NHP dose-response TBI (photon/low-LET) studies with data collected from radiation accident victims and radiation therapy patients. - Continue efforts in developing protocol for evaluating newly discovered protein biomarkers for use in human radiation accident cases. ***FY 2017 Plans:*** - Report on use of PCC assay for assessment of partial-body exposure including use of protein nucleic acid (PNA) centrometic probes for identification of di-centric aberrations in PCC assay. Expand upon radiation calibration curves using PCC assay. - Sustain participation in exercises and establishment of a clinical laboratory certification. - Establish NHP partial-body animal radiation model involving low-LET exposure with AFRRI LINAC to identify organ-specific radiation injury biomarkers evaluated earlier in low-LET TBI studies. - Continue evaluating new predictive radiation-responsive biomarkers in NHP models for ARS outcome and their applicability in humans. - Sustain efforts in comparing results from NHP dose-response TBI (photon/low-LET) studies with data collected from radiation accident victims and radiation therapy patients. - Continue to create human baseline data base for evaluated biomarkers for use in human radiation accident cases.			
Accomplishments/Planned Programs Subtotals	0.153	0.183	0.186

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY 2015

- Report on use of changes in multiple human blood cell counts on assessment of radiation dose.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603002DHA / *Medical Advanced Technology (AFRRI)*	**Project (Number/Name)** 242A / *Biodosimetry (USUHS)*

- Establish Institute's IRB regulatory approvals to permit evaluation of newly developed proteomic biomarkers for use in radiation accident cases by commercial partner.
- Provide 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) and obtain necessary FDA approval.
- Continue evaluation and validation of discovered new radiation-responsive biomarkers in higher order animals and human models for biodosimetric diagnostic applications.
- Begin to develop protocol on evaluated and newly developed protein biomarkers for use in human radiation accident cases.
- Continue to create a human baseline data base for evaluated biomarkers for use in human radiation accident cases.
- Begin to compare results from NHP dose-response TBI (photon/low-LET) studies with data collected from radiation accident victims and radiation therapy patients.

By FY 2016
- Report on the 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 evaluating new predictive radiation-responsive biomarkers in animal models for ARS outcome and their applicability in humans.
- Continue to compare results from NHP dose-response TBI (photon/low LET) studies with data collected from radiation accident victims and radiation therapy patients.

By FY 2017
- Report on development and use of AFRRI's mobile FRAT application for use in triage diagnostics of suspected radiation casualties.
- Characterize robustness of PCC assay for assessment of high-dose partial-body exposures.
- Establish NHP partial-body animal radiation model involving low-LET exposure with AFRRI LINAC to identify organ-specific radiation injury biomarkers evaluated earlier in low-LET TBI studies.
- Continue evaluating new predictive radiation-responsive biomarkers in NHP models for ARS outcome and their applicability in humans.
- Sustain efforts in comparing results/data from NHP dose-response TBI (photon/low-LET) studies with data collected from radiation accident victims and radiation therapy patients.
- Continue to create a human baseline data base for evaluated biomarkers for use in human radiation accident cases.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
242B: *Radiation Countermeasures (USUHS)*	0.508	0.102	0.122	0.124	-	0.124	0.133	0.136	0.139	0.142	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 2015	FY 2016	FY 2017
Title: Radiation Countermeasures (USUHS)	0.102	0.122	0.124

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 2015 Accomplishments:

- Continued evaluating minipig and nonhuman primate as suitable models for assessing effects of radiation countermeasures on survival and biodosimetry markers after radiation injury.

FY 2016 Plans:

- Continue evaluating minipig and nonhuman primate as suitable models for assessing effects of radiation countermeasures on survival and biodosimetry markers after radiation injury.

FY 2017 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
- Continue evaluating minipig and nonhuman primate as suitable models for assessing effects of radiation countermeasures on survival and biodosimetry markers after radiation injury			
Accomplishments/Planned Programs Subtotals	0.102	0.122	0.124

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY 2015
- Assess biomarkers in context of radiation injury and radiation countermeasure effects.

By FY 2016
- Assess biomarkers in context of radiation injury and radiation countermeasure effects.

By FY 2017
- Assess biomarkers in context of radiation injury and radiation countermeasure effects.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	2,480.064	1,177.334	1,272.109	220.916	-	220.916	212.794	234.117	240.572	243.942	Continuing	Continuing
300A: *CSI - Congressional Special Interests*	1,864.085	975.057	1,041.539	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
238C: *Enroute Care Research & Development (Budgeted) (AF)*	8.351	3.282	1.340	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	0.000	0.997	2.045	-	2.045	2.240	2.282	2.328	2.375	Continuing	Continuing
238E: *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.000	0.997	2.045	-	2.045	2.239	2.282	2.327	2.374	Continuing	Continuing
243A: *Medical Development (Lab Support) (Navy)*	97.042	31.378	37.580	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
247A: *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	0.200	0.000	2.060	2.064	-	2.064	1.548	0.000	0.000	0.000	Continuing	Continuing
247B: *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	0.425	0.000	1.040	1.135	-	1.135	1.238	0.000	0.000	0.000	Continuing	Continuing
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	6.340	2.205	1.700	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	0.000	1.003	2.349	-	2.349	2.664	2.762	2.817	2.873	Continuing	Continuing
284D: *Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)*	0.000	0.000	1.002	2.348	-	2.348	2.663	2.761	2.816	2.872	Continuing	Continuing
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	14.997	1.917	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency										Date: February 2016		
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	0.000	0.929	1.147	-	1.147	1.350	1.360	1.387	1.415	Continuing	Continuing
285C: *Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	0.000	0.928	1.147	-	1.147	1.349	1.360	1.387	1.415	Continuing	Continuing
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	29.236	10.792	8.173	7.725	-	7.725	5.034	9.230	11.169	11.392	Continuing	Continuing
307C: *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.000	1.500	-	1.500	2.235	2.375	2.463	2.512	Continuing	Continuing
307D: *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.000	1.000	1.500	-	1.500	2.235	2.375	2.463	2.512	Continuing	Continuing
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	7.616	4.544	1.180	1.160	-	1.160	1.560	1.640	1.673	1.706	Continuing	Continuing
308C: *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.503	1.500	-	1.500	1.497	1.501	1.531	1.562	Continuing	Continuing
308D: *Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	0.000	1.502	1.499	-	1.499	1.497	1.500	1.530	1.561	Continuing	Continuing
309A: *Regenerative Medicine (USUHS)*	13.908	8.388	9.489	7.323	-	7.323	7.373	8.327	10.209	10.413	Continuing	Continuing
373A: *GDF - Medical Technology Development*	296.680	99.064	116.294	139.454	-	139.454	134.790	147.378	147.764	149.276	Continuing	Continuing
378A: *CoE-Breast Cancer Center of Excellence (Army)*	25.042	7.907	7.299	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency										Date: February 2016		
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	0.000	9.900	-	9.900	9.088	10.280	10.475	10.685	Continuing	Continuing
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	22.132	6.909	6.377	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	0.000	8.655	-	8.655	7.943	8.987	9.158	9.341	Continuing	Continuing
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	8.496	3.281	3.520	3.051	-	3.051	2.697	2.914	3.118	3.180	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)*	0.000	2.484	2.823	2.641	-	2.641	2.822	3.310	3.376	3.445	Continuing	Continuing
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	21.287	6.303	6.260	7.900	-	7.900	7.250	8.203	8.359	8.526	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)*	31.867	4.397	2.679	1.869	-	1.869	0.000	0.000	0.000	0.000	-	-
448A: *Military HIV Research Program (Army)*	6.663	5.270	6.589	6.070	-	6.070	6.359	7.360	7.877	8.035	Continuing	Continuing
830A: *Deployed Warfighter Protection (Army)*	14.226	4.156	5.306	4.889	-	4.889	5.123	5.930	6.345	6.472	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 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, 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.

For the Army Medical Command, the Armed Forces Pest Management Board (AFPMB) Deployed Warfighter Protection project provides for the development of new or improved protection of ground forces from disease-carrying insects.

For the Army Medical Command, three Centers of Excellence (CoE) receive medical technology development funds. The Breast Cancer CoE (Army) provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. The Gynecological Cancer CoE (Army) 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 (a medicinal preparation created by a biological process used to treat diseases) for the management of gynecological disease. Management of the Breast and Gynecological Cancer CoEs will 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.

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603115DHA *I Medical Technology Development*

In FY 2015, 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, Orthopedics, 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, and Epilepsy. CSI funds were also provided for Joint Warfighter Medical Research, Orthotics and Prosthetics Outcomes, HIV/AIDS Program Increase, Global HIV/AIDS Prevention, and Restore Core Research Funding Reduction. 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 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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	226.131	231.051	250.488	-	250.488
Current President's Budget	1,177.334	1,272.109	220.916	-	220.916
Total Adjustments	951.203	1,041.058	-29.572	-	-29.572
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	970.934	1,041.539			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-19.731	-			
• Federally Funded Research and Development Center (FFRDC) Reduction	-	-0.481	-	-	-
• Realignment of the Medical Development Laboratory Support Program	-	-	-38.211	-	-38.211
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-13.599	-	-13.599
• Restore USUHS Breast, GYN, and Prostate Cancer Centers of Excellence	-	-	8.547	-	8.547
• Rebalance Joint Program Committees	-	-	13.691	-	13.691

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Project: 300A: *CSI - Congressional Special Interests*		
Congressional Add: *245A - Amyotrophic Lateral Sclerosis (ALS) Research*	7.500	7.500
Congressional Add: *293A - Autism Research*	6.000	7.500
Congressional Add: *296A - Bone Marrow Failure Disease Research*	3.200	3.000
Congressional Add: *310A - Peer-Reviewed Ovarian Cancer Research*	20.000	20.000
Congressional Add: *328A - Multiple Sclerosis Research*	5.000	6.000
Congressional Add: *335A - Peer-Reviewed Cancer Research*	50.000	50.000

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603115DHA *I Medical Technology Development*

Congressional Add Details ($ in Millions, and Includes General Reductions)	**FY 2015**	**FY 2016**
Congressional Add: *336A - Peer-Reviewed Lung Cancer Research*	10.500	12.000
Congressional Add: *337A - Peer-Reviewed Orthopedic Research*	30.000	30.000
Congressional Add: *338A - Peer-Reviewed Spinal Cord Research*	30.000	30.000
Congressional Add: *339A - Peer-Reviewed Vision Research*	10.000	10.000
Congressional Add: *352A - Traumatic Brain Injury/Psychological Health Research*	105.000	97.792
Congressional Add: *380A - Peer-Reviewed Breast Cancer Research*	120.000	120.000
Congressional Add: *390A - Peer-Reviewed Prostate Cancer Research*	80.000	80.000
Congressional Add: *392A - Gulf War Illness Peer-Reviewed Research*	20.000	20.000
Congressional Add: *396A - Research in Alcohol and Substance Use Disorders*	4.000	4.000
Congressional Add: *400A - Peer-Reviewed Medical Research*	247.500	278.700
Congressional Add: *417A - Peer-Reviewed Alzheimer Research*	12.000	15.000
Congressional Add: *439A - Joint Warfighter Medical Research*	30.000	30.000
Congressional Add: *452A - Peer-Reviewed Reconstructive Transplant Research*	15.000	12.000
Congressional Add: *454A - Orthotics and Prosthetics Outcomes Research*	10.000	10.000
Congressional Add: *456A - HIV/AIDS Program*	12.900	12.900
Congressional Add: *459A - Peer-Reviewed Epilepsy Research*	7.500	7.500
Congressional Add: *463A – Program Increase: Restore Core Research Funding Reduction (GDF)*	94.584	138.509
Congressional Add: *474A – Program Increase: Restore Core Research Funding Reduction (Army)*	7.575	1.457
Congressional Add: *474B – Program Increase: Restore Core Research Funding Reduction (Navy)*	6.856	0.000
Congressional Add: *474C – Program Increase: Restore Core Research Funding Reduction (Air Force)*	10.228	2.928
Congressional Add: *474D – Program Increase: Restore Core Research Funding Reduction (USUHS)*	2.514	2.553
Congressional Add: *495 - Peer-Reviewed Tick-Borne Disease Research*	0.000	5.000
Congressional Add: *496 -Trauma Clinical Research Program*	0.000	10.000
Congressional Add: *540A - Global HIV/AIDS Prevention (Navy)*	8.000	8.000
Congressional Add: *660A - Tuberous Sclerosis Complex (TSC)*	6.000	6.000
Congressional Add: *790A - Duchenne Muscular Dystrophy*	3.200	3.200
Congressional Add Subtotals for Project: 300A	975.057	1,041.539

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603115DHA *I Medical Technology Development*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Congressional Add Totals for all Projects	975.057	1,041.539

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0603115-Medical Technology Development (-$19.731 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$19.731 million).

FY 2015: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0603115-Medical Technology Development (+$970.934 million).

FY 2016: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0603115-Medical Technology Development (+$1041.539 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 RDT&E PE 0603115 (+$13.691M) from DHP RDTE PE 0604110 (-$13.403) and from DHP RDT&E PE 0605145 (-0.288M).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
300A: *CSI - Congressional Special Interests*	1,864.085	975.057	1,041.539	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

In FY 2015, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2015 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, Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis, Cancer, Lung Cancer, Orthopedic, Spinal Cord, Vision, Traumatic Brain Injury and Psychological Health, Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer's Research, Joint Warfighter Medical Research, Reconstructive Transplant, Tuberous Sclerosis Complex, Duchenne Muscular Dystrophy, Orthotics and Prosthetics Outcomes, HIV/AIDS program increase, Global HIV/AIDS Prevention, Epilepsy, and Restore Core Research Funding Reduction. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research	7.500	7.500
FY 2015 Accomplishments: This Congressional Special Interest initiative provided funds for research in Amyotrophic Lateral Sclerosis (ALS). ALS is a degenerative neuronal 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, 2015 the Therapeutic Development Award and the Therapeutic Idea Award. Applications were received in August 2015 followed by scientific peer review in October 2015. Funding recommendations were made at programmatic review in December 2015. Awards will be made by September 2016.		
FY 2016 Plans: This Congressional Special Interest initiative is for Amyotrophic Lateral Sclerosis (ALS) Research.		
Congressional Add: 293A - Autism Research	6.000	7.500
FY 2015 Accomplishments: This Congressional Special Interest initiative provided funds for research in Autism Research, 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. The Autism Research Program funds research at universities, hospitals, nonprofit and for-profit institutions. Two award mechanisms were released in April 2015, the Clinical Trial Award and the Idea Development Award. Applications		

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016
were received in October 2015 followed by scientific peer review in December 2015. Funding recommendations will be made at programmatic review in February 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Autism Research.		
Congressional Add: 296A - Bone Marrow Failure Disease Research ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative funded research for bone marrow failure diseases. The mission of the 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 2015, applications were accepted through one funding opportunity, the Idea Development Award, released in March 2015. Applications were received in July 2015 followed by scientific peer review in September 2015. Funding recommendations were made at programmatic review in November 2015. Award(s) will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Bone Marrow Failure Disease Research.	3.200	3.000
Congressional Add: 310A - Peer-Reviewed Ovarian Cancer Research ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative funded research in Ovarian Cancer. In striving to achieve the goal of eliminating ovarian cancer, the Ovarian Cancer Research Program (OCRP) is challenging the research community to address high impact, innovative research. The FY 2015 OCRP supported innovative ideas that provide new paradigms, leverages critical resources, facilitates synergistic, multidisciplinary partnerships, and cultivates the next generation of investigators in ovarian cancer. Five award mechanisms were offered: Pilot Award, Clinical Translational Award, Investigator-Initiated Research Award, Ovarian Cancer Academy Award recruiting Early-Career Investigators, and the Outcomes Consortium Award. Application submission deadlines were in August 2015 and in September 2015 followed by scientific peer reviews in September and October 2015. Funding recommendations were made at the programmatic reviews in December 2015. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Ovarian Cancer Research.	20.000	20.000
Congressional Add: 328A - Multiple Sclerosis Research ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative funded research in Multiple Sclerosis (MS). The mission of the program is to support pioneering concepts and high-impact research relevant to the prevention, etiology (causes or origins of), pathogenesis (the mechanism(s) that cause(s) MS or the	5.000	6.000

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016
development of MS), assessment, and treatment of MS. Two award mechanisms were offered: Investigator-Initiated Research Award and Pilot Clinical Trial Award. Applications were received in September 2015 followed by scientific peer review in November 2015. Funding recommendations will be made at programmatic review in January 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Multiple Sclerosis Research.		
Congressional Add: 335A - Peer-Reviewed Cancer Research ***FY 2015 Accomplishments:*** This Congressional Special Interest research initiative was for the study of cancers designated by Congress. 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. The funds appropriated by Congress were directed for research in the following areas: colorectal cancer, genetic cancer research, kidney cancer, Listeria vaccine for cancer, liver cancer, 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), myeloproliferative disorders (abnormal growth of blood cells in bone marrow), neuroblastoma, pancreatic cancer and stomach cancer. Three award mechanisms to support these topic areas were released in April 2015: the Career Development Award, the Idea Award with Special Focus, and the Translational Team Science Award. One additional funding opportunity, the Horizon Award, was released in July 2015. Applications were received in August and September 2015 followed by scientific peer review in November and December 2015. Funding recommendations will be made at programmatic review in February 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Cancer Research.	50.000	50.000
Congressional Add: 336A - Peer-Reviewed Lung Cancer Research ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative funded research in Lung Cancer. The goal of the Peer-Reviewed Lung Cancer Research Program is to eradicate deaths from lung cancer to better the health and welfare of military Service members, Veterans, their families, and the American public. This research effort offered five award mechanisms in FY 2015: the Career Development, the Clinical Exploration, the Concept, the Expansion and the Idea Development Awards. Applications were received in August and September 2015 followed by scientific peer review in October and November 2015. Funding recommendations will be made at programmatic review in January 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Lung Cancer Research.	10.500	12.000
Congressional Add: 337A - Peer-Reviewed Orthopedic Research	30.000	30.000

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
FY 2015 Accomplishments: This Congressional Special Interest research initiative supported 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 overall goal of the Peer-Reviewed Orthopedic Research Program is to provide all Warriors affected by orthopedic injuries sustained in the defense of our Constitution the opportunity for optimal recovery and restoration of function. Three award mechanisms were offered in FY 2015: Clinical Trial Award, Orthopedic Care and Rehabilitation Consortium Award, and the Applied Research Award. Applications were received in the fall of 2015 followed by scientific peer review in February 2016. Funding recommendations will be made at programmatic review in April 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Orthopedic Research.		
Congressional Add: 338A - Peer-Reviewed Spinal Cord Research	30.000	30.000
FY 2015 Accomplishments: This Congressional Special Interest research initiative supported Spinal Cord Injury (SCI) research program (SCIRP). The FY 2015 SCIRP challenged the scientific community to design innovative research that will foster new directions for and address neglected issues in the field of SCI-focused research. Applications from investigators within the military Services, and applications involving multidisciplinary collaborations among academia, industry, the military Services, the Department of Veterans Affairs (VA), and other federal Government agencies were highly encouraged. The SCIRP identified three Areas of Encouragement for the FY 2015 program: Pre-hospital, enroute care, and early hospital management of SCI; Development, validation, and timing of promising interventions to address consequences of SCI and to improve recovery; Identification and validation of best practices in SCI. Projects focused on other research areas relevant to SCI were submitted for consideration, provided that sufficient justification was included in the application. In FY 2015 four award mechanisms were released in June 2015 including: Clinical Trial, Investigator-Initiated Research, Qualitative Research, and Translational Research Awards. Pre-applications were received in July 2015, and invited full applications were received in October 2015, followed by scientific peer review conducted in December 2015. Funding recommendations were made at programmatic review in February 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Spinal Cord Research.		
Congressional Add: 339A - Peer-Reviewed Vision Research	10.000	10.000
FY 2015 Accomplishments: This Congressional Special Interest research effort for Peer-Reviewed Vision Research targeted the causes, effects and treatments of eye damage, visual deficits due to TBI and diseases that, despite their different pathogenesis (mechanisms that occur during disease development), all have a		

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
common end result -- degeneration of the critical components of the eye and impairment or loss of vision. The results of this research are intended to be used for restoration and maintenance of visual function to ensure and sustain combat readiness. Basic, translational and clinical research efforts were sought to ensure that results of scientific research will be used to directly benefit the lives of military, Veteran and civilian populations. For FY 2015, the VRP focused on 1) prevention and early diagnostic, intervention and mitigation strategies for specific injuries, 2) advanced deployable devices to diagnose traumatic eye injuries, and 3) epidemiological research of military eye trauma and TBI-related vision dysfunction. To meet the goals of the program, one award mechanism was used to support vision research, the Translational Research Award. A program announcement was released in July 2015, pre-applications were received in September 2015, and applications were received in December 2015. Scientific peer review was conducted in in February 2016 with programmatic review occurring in April 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Vision Research.		
Congressional Add: 352A - Traumatic Brain Injury/Psychological Health Research	105.000	97.792
FY 2015 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest research program 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 TBI/PH research program supported projects aligned with the National Research Action Plan, 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, program announcements were released to solicit applications that address these priorities. The Neurosensory and Rehabilitation Research Award program announcement supported 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. The FY 2015 Comprehensive Universal Prevention Health Promotion Intervention Award program announcement was released in September 2015.Scientific peer and programmatic reviews will follow, and awards for selected applications will be made no later than September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Traumatic Brain Injury/Psychological Health Research.		
Congressional Add: 380A - Peer-Reviewed Breast Cancer Research	120.000	120.000

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
FY 2015 Accomplishments: This Congressional Special Interest research initiative was 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 ten overarching challenges, which were focused on preventing breast cancer, identifying what makes the breast susceptible to cancer, determining why some women get breast cancer while others do not, distinguishing aggressive breast cancer from indolent cancers, conquering the problems of over-diagnosis and overtreatment, identifying what drives breast cancer growth and determining how to stop it, identifying why some breast cancers become life-threatening metastases, determining how to prevent recurrence, revolutionizing treatment regiments with safe and effective interventions, and eliminating the mortality associated with metastasis. To support the program's vision of ending breast cancer, five award mechanisms were developed to support meritorious breast cancer research: Breakthrough Award Levels 1 and 2, Breakthrough Award Levels 3 and 4, Distinguished Investigator Award, Era of Hope Scholar Award, and Innovator Award. The Breakthrough Award accepts applications under four funding levels, depending on the scope of the research project, which could range from initial proof-of-concept to clinical trials. Program Announcements were released in March and July 2015. Application submission deadlines were in April, July, November, and December 2015. Scientific peer reviews were held in June and September 2015 and in February 2016. Programmatic reviews were held in August and November 2015 and in January and April 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Breast Cancer Research.		
Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research	80.000	80.000
FY 2015 Accomplishments: This Congressional Special Interest research was for Prostate Cancer research. The vision for this effort is 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 Prostate Cancer Research Program (PCRP) developed four overarching challenges to be addressed by the research community: (1) develop better tools for early detection of clinically relevant disease, (2) distinguish aggressive from indolent disease in men newly diagnosed with 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. To meet these goals for FY 2015, the following seven award mechanisms were developed: Collaborative Undergraduate HBCU Student Summer Training Award, Exceptional Responders Award, Health Disparity Research Award, Idea		

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
Development Award, Impact Award, Physician Research Training Award, and Postdoctoral Research Training Award. All Program Announcements were released in May 2015. Application submissions were received in August and September 2015, andscientific peer review was conducted in October and November 2015. Funding recommendations for these mechanisms were made at programmatic reviews in January and February 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Prostate Cancer Research.		
Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research	20.000	20.000
FY 2015 Accomplishments: This Congressional Special Interest research initiative was for Gulf War Illness research. The program's vision of improving the health and lives of Veterans who have the complex symptoms known as Gulf War Illness was addressed through the funding of innovative research to identify effective treatments, to improve its definition and diagnosis, and to better understand its pathobiology (study of structural and functional manifestations of a disease with emphasis on the biological aspects) and symptoms. Applications were accepted for FY 2015 through six award mechanisms: the Clinical Trial Award, the Innovative Treatment Evaluation Award, the Investigator-Initiated Research Award, the Investigator-Initiated Research Expansion Award, the Gulf War Illness Epidemiology Research Award, and a New Investigator Award. Applications were received in October 2015 followed by scientific peer review conducted in January 2016. Funding recommendations will be made at programmatic review in March 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Gulf War Illness Peer-Reviewed Research.		
Congressional Add: 396A - Research in Alcohol and Substance Use Disorders	4.000	4.000
FY 2015 Accomplishments: This Congressional Special Interest initiative was for Alcohol and Substance Abuse Disorders research. To support the program's vision of decreasing the clinical impact of alcohol and substance abuse, the Alcohol and Substance Abuse Research Program Consortium Award Program Announcement was released in January of 2015. Although initially funded under FY 2014, option year two for the selected award from this announcement will be supported with FY 2015 funds. The goal of this award mechanism it to organize multidisciplinary team-based translational research efforts to identify promising compounds, conduct proof of principle basic research to determine which compounds are most appropriate for		

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
human research trials, and conduct proof of principle trials with promising compounds. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Research in Alcohol and Substance Use Disorders.		
Congressional Add: 400A - Peer-Reviewed Medical Research ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative for the Peer-Reviewed Medical Research Program continued to strive for its vision to improve the health and well-being of all military Service members, Veterans, and beneficiaries by supporting military health-related research of exceptional scientific merit. Applications were required to address at least one of the following 41 Congressionally-directed topics: Acupuncture, Acute Lung Injury, Advanced Prosthetics, Arthritis, Burn Pit Exposure, Cardiovascular Health, Chronic Migraine and Posttraumatic Headache, Congenital Heart Disease, Dengue, Diabetes, DNA Vaccine Technology for Postexposure Prophylaxis, Dystonia, Focal Segmental Glomerulosclerosis, Food Allergies, Fragile X Syndrome, Healthcare-acquired Infection Reduction, Hepatitis B, Hereditary Angioedema, Hydrocephalus, Inflammatory Bowel Disease, Integrative Medicine, Interstitial Cystitis, Lupus, Malaria, Metals Toxicology, Mitochondrial Disease, Nanomaterials for Bone Regeneration, Osteoarthritis, Pancreatitis, Pathogen-inactivated Dried Plasma, Polycystic Kidney Disease, Post-Traumatic Osteoarthritis, Psychotropic Medications, Pulmonary Fibrosis, Respiratory Health, Rheumatoid Arthritis, Scleroderma, Sleep Disorders, Tinnitus, Vascular Malformations, and Women's Heart Disease. Five award mechanisms were offered in FY 2015: the Clinical Trial Award, the Discovery Award, the Focused Program Award, the Investigator-Initiated Research Award, and the Technology/Therapeutic Development Award. For the Discovery Award, application receipt occurred in July 2015, scientific peer review was conducted in September 2015, and funding recommendations were made during programmatic review in November 2015. For the remaining mechanisms, application receipt occurred in October 2015, peer review was conducted in December 2015, and funding recommendations were made during programmatic review in February 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Medical Research.	247.500	278.700
Congressional Add: 417A - Peer-Reviewed Alzheimer Research ***FY 2015 Accomplishments:*** This Congressional Special Interest research program was to study Alzheimer's disease. The Peer-Reviewed Alzheimer Research Program is devoted to (1) understanding the association between TBI and Alzheimer's disease (AD); and (2) reducing the burden on affected individuals and caregivers, especially in the military and Veteran communities. In FY 2015, the program offered three funding mechanisms	12.000	15.000

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
in order to meet the program's mission: the Convergence Science Research Award (CSRA), Quality of Life Research Award (QUAL), and Military Risk Factors Research Award (MRFA). For FY 2015, the 6 focus areas included (1-Genomics/Proteomics/Bioinformatics, 2-Pathology of Tau, 3-Roles of Non-Neuronal Cells in TBI/AD Pathogenesis 4-Imaging, 5-Care Interventions and Quality of Life and 6-Caregiver Support, and 7-Novel Target Identification). The FY 2015 CSRA mechanism requested research to investigate the linkages between TBI and AD. The intent of the FY 2015 QUAL mechanism was to fund research with the potential to benefit individuals suffering from the symptoms of TBI or AD, while reducing caregiver burden. The intent of the FY 2015 MRFA mechanism was to facilitate high-impact, systematic, population-based research investigating the association between TBI and the subsequent development of AD. The FY 2015 Program Announcements were released in the Summer of 2015, with pre-applications and full applications receipt, peer review, and programmatic review thereafter. FY 2015 awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Alzheimer Research.		
Congressional Add: 439A - Joint Warfighter Medical Research	30.000	30.000
FY 2015 Accomplishments: The Joint Warfighter Medical Research Program (JWMRP) aimed to provide continuing support for promising previously funded Congressional Special Interest (CSI) projects. 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 JWMRP directly supports military medical research in medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, radiation health effects, and clinical and rehabilitative medicine. For the FY 2015 JWMRP, 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 and full application for the next level of effort. The external scientific peer review was in May 2015 and the programmatic review occurred in June 2015. Awards will be completed by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Joint Warfighter Medical Research.		
Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research	15.000	12.000
FY 2015 Accomplishments: This Congressional Special Interest research initiative for Reconstructive Transplant Research (RTR) is to accelerate the movement of promising ideas in restorative transplantation into clinical application. The initiative is intended to support both new and established scientists across a broad spectrum of disciplines in research projects that are likely to have a major impact on RTR. The FY 2015 program		

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
will include 4 award mechanisms, covering research from early hypothesis development to clinical research. Proposal receipt is projected for the first quarter of FY 2016, with peer and programmatic review concluding in the second quarter. These awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Reconstructive Transplant Research.		
Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research ***FY 2015 Accomplishments:*** For FY 2015, the Orthotics and Prosthetics Outcomes Research Program (OPORP) offered two Program Announcements: The Orthotics Outcomes Research Award (OORA), and the Prosthetics Outcomes Research Award (PORA). Both Awards are intended to support research that evaluates the comparative effectiveness of and functional outcomes associated with relevant device clinical interventions, and/or other rehabilitation interventions for Service members and Veterans who have undergone limb salvage or limb amputation. The results of this research are intended to improve our understanding of and ultimately the implementation of the most effective prosthetic prescription, treatment, rehabilitation, and secondary health effect prevention options for patients, clinicians, other caregivers, and policymakers. Basic, translational and clinical research efforts are sought to ensure that results of scientific research will be used to directly benefit the lives of military, Veteran and civilian populations. Studies were sought that: compare different standard care approaches, include patient-centric outcome assessments, have the potential to lead to new knowledge that can be developed into new clinical practice guidelines and/or new prescription algorithms for prosthetic and orthotic devices, therefore improving patient outcomes, provide information on quality of life, reintegration, and/or return to duty as it pertains to those patients who use a prosthetic or orthotic device due to limb trauma. Studies may also be proposed that consider outcome factors related to health care delivery and clinical decision-making such as cost, accessibility, adoption of medical policy, and patient preferences. Studies should have a clinical focus, and may include methodologies and designs such as surveys, retrospective data analyses, simulation modeling, longitudinal observation, cross sectional observation, case control, or qualitative research study designs. Collaboration with military researchers and clinicians was encouraged. Joint DoD-VA studies, including longitudinal outcome studies, were particularly sought. The FY 2015 Program Announcement was released in July 2015 pre-applications and applications were due in August and November 2015, scientific peer review will be held in January 2016, and programmatic review will occur in March 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Orthotics and Prosthetics Outcomes Research.	10.000	10.000
Congressional Add: 456A - HIV/AIDS Program	12.900	12.900

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
FY 2015 Accomplishments: This Congressional Special Interest research 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. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for HIV/AIDS Program.		
Congressional Add: 459A - Peer-Reviewed Epilepsy Research ***FY 2015 Accomplishments:*** This Congressional Special Interest research initiative was for Peer-Reviewed Epilepsy Research. This was a new program in 2015. The program will support studies to examine the interconnection between traumatic brain injury and epilepsy. Longitudinal epidemiological research, including epilepsy surveillance will be studied within the context of improving patient care. Mechanistic research to examine how brain injury produces epilepsy and potential preventative avenues will be encouraged as focus areas for research. The Idea Development Award Program Announcement were released in July 2015, with pre-applications and applications were received in August and November 2015. Scientific peer review will be held in February 2015 with programmatic review occurring in April 2016. Awards will be made no later than September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Epilepsy Research.	7.500	7.500
Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported 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). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported 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).	94.584	138.509
Congressional Add: 474A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported research for the Breast Cancer CoE	7.575	1.457

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
(Project 378A), Gynecological Cancer CoE (379A), Cardiac Health CoE (381A), Underbody Blast Testing (431A), Military HIV Research (448A) And Deployed Warfighter Protection (830A). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supports research for the Cardiac Health CoE (381A), Military HIV Research (448A) and Deployed Warfighter Protection (830A).		
Congressional Add: 474B – Program Increase: Restore Core Research Funding Reduction (Navy) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported Navy research efforts to Combat Antibiotic Resistant Bacteria (Projects 247A,B) and Medical Development Laboratory Support (Project 243A). ***FY 2016 Plans:*** No Funding Programmed.	6.856	0.000
Congressional Add: 474C – Program Increase: Restore Core Research Funding Reduction (Air Force) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported Air Force research in Enroute Care (Project 238C), Human Performance (284B), Operational Medicine (285A), Force Health Protection (307B), and Expeditionary Medicine (308B). ***FY 2016 Plans:*** 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).	10.228	2.928
Congressional Add: 474D – Program Increase: Restore Core Research Funding Reduction (USUHS) ***FY 2015 Accomplishments:*** FY 2015 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) and Pain CoE (382B). ***FY 2016 Plans:*** 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).	2.514	2.553
Congressional Add: 495 - Peer-Reviewed Tick-Borne Disease Research ***FY 2015 Accomplishments:*** N/A ***FY 2016 Plans:*** This Congressional Special Interest was new in FY 2016. The initiative was directed to address research studying under-funded or gap areas of tick borne disease and will incorporate military priorities and	0.000	5.000

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
relevance where applicable. Award mechanisms will be offered through Program Announcements, followed by scientific peer review and programmatic review of submitted proposals. Funding recommendations and awards will be made by September 2017.		
Congressional Add: 496 -Trauma Clinical Research Program ***FY 2015 Accomplishments:*** N/A ***FY 2016 Plans:*** This Congressional Special Interest (CSI) was new in FY 2016 and was directed to advance trauma 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 with core DHP RDTE program funding for future planning and execution of a Request for Proposals and future award for a Trauma Clinical Research Network.	0.000	10.000
Congressional Add: 540A - Global HIV/AIDS Prevention (Navy) ***FY 2015 Accomplishments:*** This Congressional Special Interest project supports Global HIV/AIDS Prevention research. Program emphasis is placed on (1) building a national research infrastructure by funding large, multidisciplinary program projects focused on detection; (2) encouraging innovative approaches to research by funding new ideas and technology with or without supporting preliminary data; and (3) recruiting new, independent investigators for careers in research, as well as more senior investigators new to the research field. The strategy for the FY 2015 Congressional 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 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.	8.000	8.000

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
The HIV/AIDS Prevention Program provided technical assistance and resource support for 22 foreign defense forces in FY 2015. Accomplishments include over 59,000 individuals that received testing and counseling services for HIV; over 80 testing facilities (laboratories) supported with the capacity to perform clinical lab tests; 99,155 military members and their dependents targeted with HIV prevention interventions; more than 180 health care workers successfully completing an in-service training program; and support of 12,195 pregnant women with HIV testing and counseling services. ***FY 2016 Plans:*** This Congressional Special Interest project supports Global HIV/AIDS Prevention research. Program emphasis is placed on (1) building a national research infrastructure by funding large, multidisciplinary program projects focused on detection; (2) encouraging innovative approaches to research by funding new ideas and technology with or without supporting preliminary data; and (3) recruiting new, independent investigators for careers in research, as well as more senior investigators new to the research field. The strategy for the FY 2015 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 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 and accomplishments for FY 2015 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)	6.000	6.000
FY 2015 Accomplishments: The Congressional Special Interest research initiative for Tuberous Sclerosis Complex (TSC) encouraged 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. Within this context, the FY 2015 TSC research program encouraged applications that address vital		

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016
program focus areas for mechanisms underlying clinical manifestations and/or novel therapeutic strategies. This research effort offered three award mechanisms to support TSC research: Idea Development, Exploration-Hypothesis Development, and Pilot Clinical Trial Awards. Applications were received in July 2015, followed by scientific peer review conducted in September 2015, and funding recommendations were made at programmatic review in December 2015. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Tuberous Sclerosis Complex (TSC) Research.		
Congressional Add: 790A - Duchenne Muscular Dystrophy ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative was for research focused on Duchenne Muscular Dystrophy (DMD) (gene mutations in skeletal muscle proteins affecting approximately 1 in 3,600 boys causing muscle degeneration and eventual death). The goal for this research program is to extend and improve the function, quality of life, and lifespan for all individuals diagnosed with DMD by supporting research to better inform the development of drugs, devices, and other interventions and promote their effective clinical testing. This program encourages applications that address: 1- discovery and qualification of pharmacodynamic (the biochemical and physiological effects of drugs on the body, their mechanisms of action, and the relationship between drug concentration and effect), prognostic, and predictive biomarkers; 2- assessment of clinical trial outcomes; 3- extension or expansion of preclinical translational data; and 4- novel interventions to improve clinical care and quality of life. A total of three award mechanisms were offered in 2015, the Investigator-Initiated Research Award, the Translational Leverage Award and the Therapeutic Idea Award. Applications were received in October 2015 with scientific peer review was conducted in January 2016 and programmatic review will be conducted in March 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Duchenne Muscular Dystrophy Research.	3.200	3.200
Congressional Adds Subtotals	975.057	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.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
238C: *Enroute Care Research & Development (Budgeted) (AF)*	8.351	3.282	1.340	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 2015	FY 2016	FY 2017
Title: Enroute Care Research & Development (Budgeted) (AF)	3.282	1.340	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 2015 Accomplishments:

Evaluated the life-saving interventions performed or attempted by medics in the pre-hospital/pre-surgical setting to improve training of medics prior to deployment to a combat zone. Informed the development of management strategies that decrease post-treatment morbidity and mortality. Evaluated the current documented care of patients during tactical evacuation (TACEVAC) from point of injury to treatment facility to develop evidence-based clinical practice guidelines (CPGs). Assessed the En-Route use of opioids, ketamine and epidural analgesia for improved treatment of pain in patients transported by Critical Care Air Transport Teams (CCATT). Evaluated a restrictive red cell transfusion approach prior to evaluation to reduce blood use, decrease morbidity, and provide evidence for clinical practice guidelines for traumatically injured and severely burned patients transported or evacuated. Established the Joint En-Route Care Consortium (J-ERC) to integrate and coordinate ERC research efforts and

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
to provide input on the transition of research findings into fielded products, clinical guidance, and policies. Transitioned the Comprehensive Adult Extracorporeal Membrane Oxygenation (ECMO) Support Program. ***FY 2016 Plans:*** 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 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.			
Accomplishments/Planned Programs Subtotals	3.282	1.340	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, PE 0807714HP: *Other Consolidated Health Support*	13.441	13.844	14.259	-	14.259	14.655	-	-	-	Continuing	Continuing

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
238D: *Core Enroute Care R&D - Clinical Translational Focus (AF)*	0.000	0.000	0.997	2.045	-	2.045	2.240	2.282	2.328	2.375	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 2015	FY 2016	FY 2017
Title: Core Enroute Care R&D - Clinical Translational Focus (AF)	0.000	0.997	2.045

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 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
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.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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. 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.			
Accomplishments/Planned Programs Subtotals	0.000	0.997	2.045

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
238E: *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.000	0.997	2.045	-	2.045	2.239	2.282	2.327	2.374	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 2015	FY 2016	FY 2017
Title: Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)	0.000	0.997	2.045

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 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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:*** 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.			
Accomplishments/Planned Programs Subtotals	0.000	0.997	2.045

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
243A: *Medical Development (Lab Support) (Navy)*	97.042	31.378	37.580	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 2015	FY 2016	FY 2017
Title: Medical Development (Lab Support) (Navy)	31.378	37.580	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 2015 Accomplishments:

Provided operating and miscellaneous support costs for eight medical RDT&E labs across 15 research focus areas that aim to protect, treat, rehabilitate and enhance the performance of the Warfighter. Funding supported civilian personnel costs, as well as the acquisition of technologically advanced cutting edge research equipment for research and data acquisition, automated sampling, and real time statistical analysis of biomedical research data utilizing data information systems integral with new equipment. Continued to provide replacement of obsolete, general purpose research equipment.

FY 2016 Plans:

Continue to provide 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:

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Funding for Medical Development (Lab Support) (Navy) was realigned to Program Element (PE) 0606105 - Medical Program-Wide Activities.			
Accomplishments/Planned Programs Subtotals	31.378	37.580	0.000

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
247A: *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	0.200	0.000	2.060	2.064	-	2.064	1.548	0.000	0.000	0.000	Continuing	Continuing

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: Prevent Avoidable Epidemics; Detect Threats Early; and Respond Rapidly and Effectively to biological threats of international concern.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Elimination of Malaria in Southeast Asia (CARB) (Navy)	0.000	2.060	2.064
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 2015 Accomplishments: No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative.			
FY 2016 Plans: The first objective of this project, which was to enhance the malaria surveillance in Vietnam, was completed in FY14. The malaria surveillance system was optimized to define exactly where transmission is occurring with novel mapping to support targeted interventions and the monitoring and evaluation of their impact. It built upon existing funded projects, leveraging investments from the US Government, international partners and non-Government Agencies.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
In FY15, surveillance efforts started in 2014 expanded to include military personnel, a mobile group working in malaria endemic areas of Vietnam. This population has traditionally been excluded from global malaria control programs and comprehensive malaria burden data is not available. The Vietnamese People's Army Military Medicine Department (MMD) requested a cross-sectional study be conducted to determine the parasite carriage rate and proportion of drug-resistant parasites within the military. This study was critical to understanding the malaria burden in this segment of the Vietnamese population and is a pre-requisite for additional malaria elimination efforts planned for FY16. In FY16, after establishing a baseline parasite carriage rate and drug resistant burden in FY15 for the military, research efforts will focus on improving the quality of detecting individuals carrying the malaria parasite, treatment (the drugs themselves and the adherence to them) and the implementation of rigorous investigation of each case to determine the origin of infection to prevent further infections. The impact of the malaria interventions under study will be evaluated (and re-evaluated) to determine which quality improvement practices should be scaled up or if additional interventions are needed. The most effective combinations of interventions for different epidemiological strata in Vietnam will be determined to select and then directly evaluate the impact of the selected interventions on malaria parasite carriage and disease rates in an on-going iterative fashion (operations research). Collected malaria surveillance and intervention data will be modelled to measure impact of previous interventions in Vietnam. The most promising intervention or combination of interventions will be recommended for deployment for eliminate malaria in the defined geographic region of study in Vietnam. ***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 most promising intervention or combination of interventions will be deployed to demonstrate the feasibility of eliminating malaria in defined geographic regions of Vietnam. FY17 funding will also be used to cover complementary therapeutic efficacy trials of antimalarial drugs that will assist investigators to better understand drug sensitivity in the region. These additional studies will also support the identification of molecular markers of malaria drug resistance.			
Accomplishments/Planned Programs Subtotals	0.000	2.060	2.064

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
247B: *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	0.425	0.000	1.040	1.135	-	1.135	1.238	0.000	0.000	0.000	Continuing	Continuing

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 Antimicrobial Resistance; Prevent Avoidable Epidemics; Detect Threats Early; and Respond Rapidly and Effectively to biological threats of international concern

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)	0.000	1.040	1.135
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 2015 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative. ***FY 2016 Plans:*** FY14 efforts were directed towards the development and approval of research protocols by NAMRU-3 and Ministry of Health Scientific Review Board and Institutional Review Board, as well as, the development of agreements, securing required equipment and supplies, and the recruitment of necessary contract staff to initiate patient enrollment during first quarter of FY15. FY15 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 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 will be considered for enrollment. Laboratory testing will augment the testing routinely performed at the hospital microbiology laboratory, and will include diagnostic tests (e.g. blood cultures, malaria smears, HIV tests, and serology), molecular diagnostics (e.g. microarray analysis, multiplex PCR, and sequencing), and assays measuring the host-response (biomarker assays and host transcriptome arrays). 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. FY16 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 2017 Plans:*** FY17 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 the prognostic markers for sepsis and common pathogenic pathway data to achieve improve patient outcomes.			
Accomplishments/Planned Programs Subtotals	0.000	1.040	1.135

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	6.340	2.205	1.700	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 2015	FY 2016	FY 2017
Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)	2.205	1.700	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 2015 Accomplishments:

Collected data to devise a multivariate risk model that predicts failure to return to full-duty status following disease/non-battle musculoskeletal injury as a surveillance program for active-duty service members, with the potential to be integrated into the current Military Medicine Standard of Care.

FY 2016 Plans:

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
magnify each other. Advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention. ***FY 2017 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	2.205	1.700	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
284C: *Core Human Performance R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.003	2.349	-	2.349	2.664	2.762	2.817	2.873	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 2015	FY 2016	FY 2017
Title: Core Human Performance R&D - Clinical Translational Focus (AF)	0.000	1.003	2.349
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 2015 Accomplishments: No funding programmed.			
FY 2016 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. Demonstrate exposure to non-hypoxic hypobaria induces subcortical white matter injury by MRI. Evaluate changes in inflammatory serum markers of hyperoxemia/oxidant stress.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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:*** 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. Examine biomarkers for cognitive and physiological performance. Continue to evaluate model of hypobaria-related white matter damage for detection of the biological/neuropathological indicators. Develop neuroprotection and/or neurotreatment therapies designed to mitigate hyperoxemic brain injury/effects. Integrate high altitude and hypoxia studies to support a mature acceleration and altitude research program focused on defining and mitigating extreme physiological and physical demands of higher altitudes to include decompression sickness and hypoxia. Continue work to determine operator/aircrew needs to optimize performance in high altitude environment to inform operational changes and determine safe altitudes for long-term exposures. Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions magnify each other. Continue to advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention.			
Accomplishments/Planned Programs Subtotals	0.000	1.003	2.349

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
284D: *Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)*	0.000	0.000	1.002	2.348	-	2.348	2.663	2.761	2.816	2.872	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 piloted aircraft, as well as remote piloted aircraft operations, aviation performance and injury prevention, and personalized optimization of performance of AF personnel. The sub-project areas include: AF Aircrew Physiology and Cognition Performance which includes pilot performance monitoring and interventions, fatigue management, AF unique 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, and identification of solutions related to Operational and Environmental Challenges to Performance.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)	0.000	1.002	2.348

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 piloted aircraft, as well as remote piloted aircraft operations, aviation performance and injury prevention, and personalized optimization of performance. The sub-project areas include: AF Aircrew Physiology and Cognition Performance which includes pilot performance monitoring and interventions, fatigue management, AF unique 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, and identification of solutions related to Operational and Environmental Challenges to Performance.

FY 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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. ***FY 2017 Plans:*** Complete capability advancement and finalize in-flight pilot respiratory monitoring system. Continue assessment of physiological measures capable of capturing physiological and cognitive state of AF pilot and operator personnel. 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 operational based vision research with a focus on platform specific critical operational vision performance.			
Accomplishments/Planned Programs Subtotals	0.000	1.002	2.348

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	14.997	1.917	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 2015	FY 2016	FY 2017
Title: Operational Medicine Research & Development (Air Force)	1.917	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 2015 Accomplishments:

Evaluated the hyperbaric oxygen organ preservation system to minimize tissue reperfusion damage of grafts and free flaps, allowing for more time to prepare the patient for the transplant, more precise matching of allografts resulting in decreased rejection, and subsequently better outcome, recovery and lower medical costs. Validated a bioabsorbable and biointegratable negative pressure wound therapy (NPWT) sponge to mitigate the need for sponge change and act as a scaffold for organization of healing in 3 dimensional defects. Transitioned a novel fractionated CO2 laser therapy treatment for hypertrophic scars into a sustainment program. Evaluated effective adjuncts to lifestyle intervention for the prevention of diabetes to result in long-term Air Force health care cost savings and better outcomes for our patient population. Provided healthy lifestyle coaching sessions to improve clinical outcomes for patients with Type 2 diabetes mellitus (T2DM). Developed a stepped care algorithm for the assessment, treatment, long-term management, and referral of patients with chronic pain. Developed a standardized way of delivering and managing pain medication and a training manual for the collaboration of the Behavioral Health Consultants with the primary care military health team (PCMs) in the management of patients of chronic pain. Provided military system research evidence of a sustainable program using existing resources available within primary care to assist PCMs in the management of

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
patients with chronic pain. Developed operating instructions for the delivery of pain management interventions in primary care using VTC or Defense Connect Online. ***FY 2016 Plans:*** No funding programmed. ***FY 2017 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	1.917	0.000	0.000

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
285B: *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	0.000	0.000	0.929	1.147	-	1.147	1.350	1.360	1.387	1.415	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 2015	FY 2016	FY 2017
Title: Core Operational Medicine R&D - Clinical Translational Focus (AF)	0.000	0.929	1.147

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 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
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,

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 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. FY16 program cost is $3.929M, UFR = $3.000M ***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			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 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. FY17 program cost is $3.147, UFR = $2.000M			
Accomplishments/Planned Programs Subtotals	0.000	0.929	1.147

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
285C: *Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	0.000	0.928	1.147	-	1.147	1.349	1.360	1.387	1.415	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 2015	FY 2016	FY 2017
Title: Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)	0.000	0.928	1.147

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 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 emergent infectious diseases. Explore an integrated operational medicine approach to characterize individual health and provide comprehensive treatment to improve human health and performance.			
Accomplishments/Planned Programs Subtotals	0.000	0.928	1.147

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	29.236	10.792	8.173	7.725	-	7.725	5.034	9.230	11.169	11.392	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 2015	FY 2016	FY 2017
Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force)	10.792	8.173	7.725
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: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017

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.

AFMS Innovation initiatives include demonstration of projects to drive, streamline, and empower continuous process improvements and innovations, leading practices, disruptive and transformative innovation into enterprise-wide efforts to enhance an agile culture of innovative through use of an innovations exchange web portal platform. Analyze genomics survey data to identify gaps in genomic education, and development of educational programs to correct these gaps. Utilize patient modeling algorithms to identify pharmacogenomics 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-depressants 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.

FY 2015 Accomplishments:

Initiated Phase II of a Clinical Utilities Study (CUS) of enrolled Air Force participants. This study assesses the value of genetic risk information on health outcomes, provides genetic risk profiles for clinically actionable conditions. The results of this study will determine how knowledge of genetic risk information can impact a participant's behavior, attitudes, healthcare utilization, and health outcomes, which will impact the future use of genetic risk information. Completed requirements development for an AFMS digital BioBank to store and analyze genomic data linked with electronic medical record information and other relevant and AF specific data. Continued research projects to develop a device for non-invasive rapid determination of hydration status, device for monitoring tissue oxygenation, multi-layer and micro-needle drug delivery, and ultrasound transducing fabrics. Continued development of laser detection prototype for in cockpit detection and risk to operator health characterization. Validated assay for detection of Trypanasoma cruzi, the etiological agent of Chagas Disease for urgent testing of high-risk military and civilian populations. Developed optimized brain control exercises for reducing tinnitus. Achieved IRB approval for initiation of FY16 protocols. Developed disease/non-battle musculoskeletal injury surveillance program for active-duty service members, and developed first-ever characterization of corrective surgery by index injury. Investigated potential biological indicators of high power microwave (HPW) exposures by characterizing biochemical events for disease processes associated with HPM exposure for early diagnosis and treatment of injuries experienced by affected military personnel. Effectively formulated successful strategies

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
in support of early detection of emerging threats by providing accurate and timely environmental situational awareness. Provided mission-directed, persistent surveillance and real-time hazard identification as key elements to deployable, operational and emerging threat monitoring and event planning for disaster preparedness and response. ***FY 2016 Plans:*** 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. 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			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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-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			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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).			
Accomplishments/Planned Programs Subtotals	10.792	8.173	7.725

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: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
307C: *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.000	1.500	-	1.500	2.235	2.375	2.463	2.512	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 2015	FY 2016	FY 2017
Title: Core Force Health Protection R&D - Clinical Translational Focus (AF)	0.000	1.000	1.500
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: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017

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 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 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			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 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.			
Accomplishments/Planned Programs Subtotals	0.000	1.000	1.500

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
307D: *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.000	1.000	1.500	-	1.500	2.235	2.375	2.463	2.512	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 2015	FY 2016	FY 2017
Title: Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)	0.000	1.000	1.500

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.

FY 2015 Accomplishments:
No funding programmed.

FY 2016 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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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.			
Accomplishments/Planned Programs Subtotals	0.000	1.000	1.500

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.)

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	7.616	4.544	1.180	1.160	-	1.160	1.560	1.640	1.673	1.706	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 2015	FY 2016	FY 2017
Title: Expeditionary Medicine Research & Development (Air Force)	4.544	1.180	1.160
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 2015 Accomplishments: Produced the Clinical Standardization Guidelines for use of progesterone in the treatment of Traumatic Brain Injury (TBI). Transitioned hydroxocobalamin as a safe, FDA approved, effective drug to reduces nitric oxide, improve blood pressure and cardiac output, improve inflammation and act as a neuroprotective agent for septic shock, cyanide induced shock and hemorrhage shock. Concluded in-theatre data enrollment of prehospital and en route analgesic use in traumatically injured patients, including number of procedures, type of procedures, effectiveness, perceived necessity and the complication rates of the attempted or performed procedures. Initiated evaluation of new treatments to decrease deaths associated with acute kidney disease (AKI). Developed a model of Aortic Hemostasis and Resuscitation (AHR) to evaluate Advanced Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA-A) for non-compressible torso hemorrhage and reversal of hemorrhage induced traumatic cardiac arrest (HiTCA). Established model to evaluate endovascular devices for repair of infrarenal aortic injury to reduce mortality due to			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
major vascular injury from noncompressible torso hemorrhage (NCTH) as the leading cause of potentially survivable trauma on the battlefield. Evaluated the abdominal aortic tourniquet application, Tactical Combat Casualty Care (TCCC) guided resuscitation and spray-dried plasma resuscitation on cardiovascular function, cardiopulmonary function and visceral tissue oxygenation to mitigate mortality due to non-compressible, pelvic junctional hemorrhage following traumatic high bilateral extremity amputation and pelvic disruption. Developed a model of bi-lateral hind limb ischemia reperfusion injury using endovascular balloon, occlusion will be developed. Characterized the immune-inflammatory and coagulation responses of traumatic hemorrhage to identify targets of FDA approved immune-inflammatory cloaking compounds that could reduce mortality and morbidity of traumatic hemorrhage. Prototyped portable sterilization technology for surgical instruments in remote settings completed and submitted to FDA for clearance.			
FY 2016 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. 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 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			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 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	4.544	1.180	1.160

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.)

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
308C: *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.503	1.500	-	1.500	1.497	1.501	1.531	1.562	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 2015	FY 2016	FY 2017
Title: Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)	0.000	1.503	1.500

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 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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. FY16 program cost is $2.047M, UFR = $0.544 ***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. FY17 program cost is $2.000M, UFR = $0.5000M			
Accomplishments/Planned Programs Subtotals	0.000	1.503	1.500

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
308D: *Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	0.000	1.502	1.499	-	1.499	1.497	1.500	1.530	1.561	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 2015	FY 2016	FY 2017
Title: Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)	0.000	1.502	1.499

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 2015 Accomplishments:
No Funding Programmed.

FY 2016 Plans:
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:

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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.			
Accomplishments/Planned Programs Subtotals	0.000	1.502	1.499

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
309A: *Regenerative Medicine (USUHS)*	13.908	8.388	9.489	7.323	-	7.323	7.373	8.327	10.209	10.413	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 2015	FY 2016	FY 2017
Title: Regenerative Medicine (USUHS)	8.388	9.489	7.323

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 108 research projects.

FY 2015 Accomplishments:

Through Sep. 2015, CNRM clinical studies have enrolled 3,795 subjects (1,981 civilian; 1,814 military). An additional 1,076 volunteers have enrolled in the CNRM screening protocols to be considered for future studies.

Through Nov. 2015, CNRM has entered 24 studies into the Federal Interagency TBI Research (FITBIR) database; additional 17 more study entries are planned by end of 2015. 32,912 Data records were submitted to FITBIR (11% of the total FITBIR records (Shared and Private) and specifically 17% of FITBIR shared records). In 2014, CNRM was the first to successfully enter data into FITBIR from a DoD study of military service members, an important precedent.

Efforts are ongoing to evaluate blast patients for a corresponding neuroimaging signature. Several cores are coordinating efforts for 7T high resolution MRI of the pathological specimens and of blast patients with persisting symptoms. In addition, PET tracers for tau are being developed and will be validated in tissues from TBI and tauopathy cases. MRI findings are being used to target neuropathological studies to improve MRI evaluation of mild TBI.

To correct PET quantification while using the Siemens mMR biograph, core staff have developed a method (patent in process) of PET attenuation correction for the head using a synthetic CT generated from MRI data. This advance will facilitate not only CNRM studies but more broadly support the growing scientific interest in combined PET-MRI as a multi-modal approach combining structural, functional, and biochemical analyses.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Through Nov. 2015, CNRM has published over 180 peer-reviewed publications. In addition, CNRM researchers have presented at numerous national and international conferences. Awarded 10 new research projects in Feb. 2015. In addition, received 46 pre-proposals in response to FY15 proposal call. After scientific screening, 29 were selected to be submitted as full applications, with anticipation of funding 10 new projects in Feb. 2016. Received several recognitions: Clinical Center Directors award to the Phenotyping core for extraordinarily successful efforts in recruitment and retention of patients in the CNRM TBI Natural History study, AlaviMandell Award for Dr. S. Roy's publication entitled,"PET Attenuation Correction Using Synthetic CT from Ultrashort EchoTime MR Imaging," Silver Award of Distinction from the Academy of Interactive & Visual Arts for CNRM communication booklet. ***FY 2016 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 FY16 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 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			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 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.”			
Accomplishments/Planned Programs Subtotals	8.388	9.489	7.323

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0806721HP: *Uniformed Services University of the Health Sciences*	8.912	9.090	9.272	-	9.272	9.458	9.647	9.840	10.036	Continuing	Continuing

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 FY15 through FY17, 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
373A: *GDF - Medical Technology Development*	296.680	99.064	116.294	139.454	-	139.454	134.790	147.378	147.764	149.276	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development provides funds 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. Medical technology development is managed by six Joint Program Committees (JPCs): 1- Medical simulation and information sciences (JPC-1) research aims to coordinate health information technology, simulation, and training research across the Medical Health System. Technology development efforts are directed toward the medical simulation task. 2- Military infectious diseases (JPC-2) research is developing protection and treatment products for military relevant infectious diseases. Technology development efforts are directed against tasks in bacterial diseases, diagnostics development, and viral diseases. 3- Military operational medicine (JPC-5) 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. Technology development efforts are directed against tasks in musculoskeletal injury; brain health and performance risk; behavioral health, wellness and resilience; warfighter physical performance; nutrition and weight balance; psychiatry and clinical psychology disorders; neurosensory performance, injury and protection; blunt, blast and accelerative injury; environmental toxicant exposure; and aircrew health and performance. 4- Combat casualty care (JPC-6) research is optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through enroute and facilities care. Technology development efforts are directed against tasks in hemorrhage, shock, and coagulopathy of trauma; TBI neurotrauma and brain dysfunction; treatments for extremity trauma, tissue injury, craniomaxillofacial injury, lung injury, and burns; pre-hospital tactical combat casualty care; enroute care; and military medical photonics. 5- Radiation health effects (JPC-7) research focuses on core capabilities to support technology development of radiation medical countermeasures development, to include demonstration of improved survivability after treatment with selected therapeutic candidates for acute radiation exposure, and identifying radioprotectants (preventative treatment) for further development. 6- Clinical and rehabilitative medicine (JPC-8) 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. 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: GDF – Medical Technology Development	99.064	116.294	139.454
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 2015 Accomplishments: FY 2015 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Medical simulation and information sciences research continued the development of an open source virtual tissue advancement model that will be open to developers and end-users, allowing them to focus on content creation into a variety of simulation system tools and for end-users to better validate simulation systems. Medical simulation also supported research to improve the realism of virtual standardized patients (avatars) used for high volume scenario rehearsal as well as for those hard-to-come-by cases, through improved artificial intelligence and realistic body language within a medical context. Medical simulation released a program announcement focused on effective ways to interface with technology through gestures or facial expressions that are relevant to military medicine. Medical simulation also requested proposals via a program announcement to improve joint enroute care methods for wounded Service members. This effort focused on the hand-offs and transfer of patients between providers. Medical simulation also supported optional 'off-the-grid' types of technology. This included different applications using static (non-dynamic) hologram technologies to provide educational training in environments that may have intermittent access to the network. Military infectious diseases research evaluated the results of the bacteriophage (a group of viruses that infect and replicate in bacteria) study to determine a path forward and a feasibility study was planned and initiated. The wound infection bacterial disease prevention and management host/pathogen biomarker project, for detection of bacterial infection in wounds, completed laboratory and initial animal studies to confirm its effectiveness and accuracy. Under antimicrobial countermeasures, clinical studies continued for the development of an antibacterial drug against multiple drug resistant bacteria and to reduce surgical site infection rates that often occur with complex combat-related wounds. A pre-Investigational New Drug (IND) meeting with the FDA indicated that additional information was required to satisfy IND requirements and the team has been working to address those requirements. Several multiyear studies selected through the FY 2014 program announcement for the development of antibacterial or other wound infection prevention strategies were initiated. Progressed in developing the capability to detect malaria, dengue, and chikungunya, achieving TRL-6 (completing safety and effectiveness testing), and prepared for transition to Medical Countermeasure Systems Joint Project Management Office for advanced development. Military operational medicine: Developed methods to mitigate decrements to operational performance and Warfighter health due to occupational exposures to repeated low level blast events. Verified performance and musculoskeletal health metrics of Service members in military training environments. Continued studies designed to determine the effectiveness of behavioral interventions to treat alcohol and substance abuse. Evaluated cognitive behavioral interventions, a type of therapy focusing on examining the relationships among thoughts, feelings and behaviors, for the treatment of posttraumatic stress disorder (PTSD). Complementary and alternative interventions were similarly concluded, as was a large scale integrated primary care/mental health care stepped approach intervention model for active duty Service members. Continued research to improve and validate skills-based interventions to build resiliency in military families and Warfighters, and interventions to improve suicide prevention and risk assessment. Evaluated interventions to promote and sustain weight loss in Warfighters and military families, and validated a policy for vitamin supplementation to reduce injuries during operational and training scenarios. Validated decision aids for managing thermal physiological work strain, the ability to perform work tasks safely in hot environments. Determined health outcomes of			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017

chemical exposures (e.g., permethrin, an insecticide used to treat uniforms). Refined biomarkers of pulmonary health resulting from exposures to toxic substances.

Combat casualty care: Hemorrhage researchers conducted non-clinical assessments of new agents to control severe internal bleeding to be administered by first responders at or near the point of injury. Researchers also evaluated the ability to modulate the immune inflammatory response in hemorrhage. TBI Neurotrauma task research screened new TBI diagnostic approaches. The enroute care task conducted research to evaluate enroute care clinical practice guidelines, the clinical impact of a spinal immobilization litter, and the collection of continuous waveform data on transported critical care patients. Treatments for extremity trauma continued to develop a specialized fracture repair product, address treatments for acute lung injury, enhance limb and craniofacial salvage, and improve wound healing by evaluating the immune response 72 hours post injury. The military medical photonics program devised and tested minimally invasive, implanted just below the skin, miniature lactate sensors, which can give almost continuous readings. Sensors have been supplied to the Army Institute for Surgical Research, where preliminary testing on animals has compared favorably to blood sample testing. Almost continuous lactate sensing is important because lactate buildup is an excellent indicator of insufficient oxygen supply to the body. Photochemical tissue bonding (PTB), developed under the program and applied to nerve repair has been transitioned to other funding, and a collaboration was developed with military surgeons at Walter Reed National Military Medical Center.This collaboration resulted in the discovery of a glass which dissolves within minutes in saline and blood for use as a stent in repairing blood vessels using PTB.

Clinical and rehabilitative medicine continued efforts and down-selected products for advanced development for neuromusculoskeletal injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Neuromusculoskeletal injury rehabilitation evaluated the safety and effectiveness of candidate medical technologies for restoration and rehabilitation products. Pain management tracked methadone and opioid related adverse events; developed novel treatments to control pain, including battlefield pain, burn pain, neuropathic (nervous system) 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, and developed nerve blocks for knee and hip arthroplasty (joint replacement) in Veterans. Regenerative medicine focused on novel approaches to engineer regeneration and repair of damaged muscle tissue, to repair nerve gap injuries, to repair blood vascular injury, and evaluated methods to prevent tissue rejection of allografts (a tissue graft from a donor). Sensory systems conducted research to verify central auditory processing disorders in blast-exposed Warfighters, evaluated computerized oculomotor vision screening to expedite the diagnosis of TBI-related oculomotor dysfunctions in a military population, tested cochlear implants for active-duty Service members, clinically assessed pharmacotherapy of hidden noise injury toward a molecular understanding of noise-induced hearing loss, developed a

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017

portable mild TBI screening device based on evaluation of a patient's gait, assessed ways to prevent noise damage to cochlear synapses, and developed a silica-collagen composite for corneal replacement.

FY 2016 Plans:

Medical simulation and information sciences research is completing the virtual tissue advancement research, which provides open source resources to enable developers to create more appropriate virtual tissue simulations. Enroute training research is addressing issues with providing training to care for wounded Service members during transport and transfer between providers. Research evaluating the effectiveness of gaming in virtual environments with combat medics is being investigated. Investigators are researching knowledge oriented medical training metrics that can best translate into reality and be sustained with optimal patient outcomes, providing educators the building blocks to create better trainers in the future and begin the long process of linking evidence-based training to patient outcomes. Medical simulation is exploring advanced adaptive tutors that incorporate adult learning techniques and neuroplasticity models so that medical personnel are not dependent on gadgets and technologies to treat a patient. Efforts towards other predictive markers that likely constitute characteristics between good and poor medical providers are being investigated. To further the advancements in augmented reality technologies for Phase II Option, medical simulation is looking into applications towards medical training that allows for validation and verification on work presently performed.

Military infectious diseases research is supporting 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 include 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 is to expand understanding of the complex microbiology inherent within combat wounds in order to lead to improved prevention and treatment. Continue ongoing efforts to develop antimicrobials and manage 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 are progressing in development for use on an FDA-approved diagnostic system to enable quicker diagnosis and treatment. These studies are in alignment with the National Strategy for Combating Antibiotic Resistance.

Military operational medicine: Define the neurological consequences of acute and repeated low level blast exposures of varying intensity and frequency in order to improve exposure standards. Perform research contributing to improved auditory injury standards for application in health hazard assessments, and for predictive models of military performance. Support the development of guidelines relating to the likelihood of musculoskeletal injury in military training and applicable to operational environments. Develop improved criteria for head supported mass, and multisensory cueing in degraded visual environments for fixed wing aircraft. Incorporate behavioral intervention regimens into clinical practice guidelines for the treatment of alcohol

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
and substance abuse. Compare cognitive behavioral interventions, which focus on examining the relationships among thoughts, feelings and behaviors for the treatment of PTSD to current standards of care. Conclude 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. Initiate large scale study for pre-/post-biomarker changes associated with psychopharmacologic, psychotherapy, and brain stimulation interventions. Refine PTSD blood-based biomarkers for transition to advanced development. Deliver validated interventions for enhanced resiliency in military families and Warfighters and more accurate suicide prevention screening tools. Develop recommendations on dietary supplement interventions to promote resiliency and sustainment of cognitive performance after brain injury. Transition policy recommendations to the Services for improving Warfighter nutrition during training and operations. Incorporate decision aids for managing thermal physiological work strain into physiological health status monitoring. Develop strategies to mitigate adverse health and disease outcomes of chemical exposures. Validate stress response biomarkers of pulmonary health resulting from exposures to toxic substances. Combat casualty care: Hemorrhage researchers are evaluating immune system modulating drugs to treat hemorrhagic shock; work is aimed at validating diagnostic and therapeutic targets for coagulopathy of trauma. TBI neurotrauma task research is starting to validate a multi-site collaborative TBI endpoints study to improve clinical trial design to inform/accelerate FDA approval of TBI diagnostic tools and therapeutic agents. Treatments for Tissue Injury continues to develop a specialized fracture repair product, address treatments for acute lung injury, enhance limb and craniofacial wound stabilization. Forward Surgical and Critical Care continues 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 continues to develop technology to detect cardiovascular collapse. Enroute care research is studying the physiological impact of patient transport and appropriate time to transport injured patients following injury. Military medical photonics is developing 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 is being redesigned for greater simplicity, longer life, and to eliminate the need for an internal battery. Commercialization of PTB for multiple clinical applications is being explored. Radiation health effects research begins technology development efforts in FY 2016 to evaluate ARS therapeutic candidates for acute radiation exposure and to develop data to support preparation of a technical data package as detailed in the Code of Federal Regulations, Chapter 21, Part 312. Clinical and rehabilitative medicine is transferring current efforts and down-selecting products to industry for neuromusculoskeletal injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Supporting development of preclinical and pilot/early-phase clinical evaluations of candidate technologies for restoration, regeneration, rehabilitation, and reintegration strategies and medical products. Neuromusculoskeletal injury is continuing research efforts focused on rehabilitation and reintegration strategies and devices; prosthetics (devices that restore function);			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
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 heterotopic ossification (bone formation in soft tissue following injury). Pain management efforts continue to track pain-related substance abuse; develop novel methods and therapeutics to control pain, including battlefield pain, burn pain, neuropathic pain, and chronic pain after amputation; study modulation of inflammatory cells as an approach to mitigate spinal cord injury neuropathic pain; study effects of peripherally administered opioids; and develop nerve blocks for knee and hip arthroplasty (joint replacement) in Veterans. Regenerative medicine is developing 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. Studying approaches for immunomodulation and immune engineering to improve outcomes and control rejection following vascularized composite allotransplantation (hand and face transplantation). Sensory systems research is advancing diagnosis, restoration and rehabilitation of injured and dysfunctional sensory systems, including vision (total orbit, cornea, retina, ocular nerve), hearing (hair cells, tympanic membrane, cochlea, auditory nerve) and balance (vestibular complex).			
FY 2017 Plans: Medical simulation and information sciences research will focus on developing prototypes of simulated skin with intent to attach to existing medical simulators or future advanced modular manikins to better equip military healthcare personnel with data and tools to make combat decisions. Will invest in existing environmental, personnel, and other related sensors in order to assess if they may provide data/information on needed military medical intelligence to improve rapid turn-around times on training tools for new injuries or incorporation of updated treatment options for injuries. Research and development will occur in the area of Machine Learning/Artificial Intelligence tools to improve predictive models that will address medical skill acquisition or minimize skill decay which may lead to policy changes for sustained training. This project will enhance patient safety and provide the Military Health System with better metrics to make evidence-based policy decisions. Options on Gesture Interface will be awarded to the best designs from Phase I and will include preliminary test and evaluation of prototyped Gesture Interface controls and sensing during medical training. Will advance medical simulation systems interoperability to share more content, data, information, etc. than currently performed from one simulation component device to another or to a System of Systems framework. Will conduct a knowledge analysis on gaps for healing, education, quality living, physiology/psychotherapy simulation tools that any and every military person could use. Military infectious diseases research will continue supporting the 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. Results of studies to develop antibacterial and clinical guidelines for better wound infection management will be evaluated for down-selection. Will progress in developing diagnostic assays for selected bacteria commonly			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
found in wound infections for use on an FDA-approved diagnostic system to improve pathogen identification times, which will guide better treatment approaches Program announcements in developing antimicrobials and treating wound infection will be released 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 are in alignment with the National Strategy for Combating Antibiotic Resistance. Military operational medicine: Researchers will collect 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. Will continue research to develop improved predictive auditory injury models in order to update acoustic injury standards for health hazard assessment. Will begin development of 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. Collect data to improve multisensory cueing criteria for aircrew performance optimization in degraded visual environments. Will utilize data collected in longitudinal assessments for dietary supplement use and correlate usage patterns with associated negative and positive health effects. Will evaluate the effects of healthy cooking on 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 Speciality assignment standards. Will complete studies to inform alcohol and substance abuse prevention and treatment intervention guidelines. Will continue work to deliver validated interventions for promoting resilience in military families and Service members. Will deliver interventions to prevent suicide behaviors and begin clinical trials to test the efficacy of the interventions. Will conclude several large scale intervention studies evaluating pharmacologic, psychotherapy, and augmented psychotherapy (virtual reality and/or pharmacologic cognitive enhancement) treatments for PTSD. Will continue to build larger scale human PTSD data and specimen banks for meta-analyses, consistent with NRAP guidelines. Will validate candidate biomarkers for exposure to inhaled or ingested toxic substances and begin to develop medical guidance for adverse health risk assessments. Will conduct research to provide validated metrics for optimized operational task performance in extreme environments. Combat casualty care: Researchers within the hemorrhage task will continue to evaluate immune system modulating drugs to treat hemorrhagic shock. Work will also be aimed at validating diagnostic and therapeutic targets for coagulopathy of trauma. Inflammatory modulation work will begin to shift focus to the time period 4 to 72 hours post injury (relevant to prolonged field care). New work in this area will begin to focus on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. TBI neurotrauma task research will continue validating a multi-site collaborative TBI endpoints study to improve clinical trial design to inform/accelerate FDA approval of TBI diagnostic tools and therapeutic agents while taking full advantage of the National Collegiate Athletic Association (NCAA)-DoD grand alliance to study TBI research. Treatments for extremity trauma will continue to develop a specialized fracture repair product and novel fracture stabilization techniques, address treatments for acute lung injury, and stabilization of limb wounds			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
and maxillofacial wounds. Forward Surgical and Critical Care will continue 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 continues to develop technology to detect cardiovascular collapse. In addition, pre-hospital research will be transitioning to advanced development, including the vascular shunt and decision-assisted tools for pre-hospital and intensive care units. The enroute care task will develop the specifications of an integrated system to support safe patient care and hand-offs, and the development of expanded enroute 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 ARS therapeutic candidates and radioprotectants for acute radiation exposure and develop data to support preparation of a technical data package, as detailed in the Code of Federal Regulations, Chapter 21, Part 312. Efforts will demonstrate general military utility. Research will develop data to support qualification of models for use in FDA approved trials. 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, regenerative medicine, and/or sensory systems (hearing, vision, and balance) after traumatic injury. 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 evaluate preclinical 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. Will conduct pre-clinical and early clinical trials to advance diagnosis, restoration and rehabilitation of injured and dysfunctional sensory systems, including vision (total orbit, cornea, retina, optic nerve), hearing (hair cells, tympanic membrane, cochlea, auditory nerve) and balance (vestibular complex).			
Accomplishments/Planned Programs Subtotals	99.064	116.294	139.454

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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C. Other Program Funding Summary ($ in Millions)

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.

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, quarterly and annual status reports, and is subject to 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
378A: *CoE-Breast Cancer Center of Excellence (Army)*	25.042	7.907	7.299	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Breast Cancer CoE (Army) 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 2015	FY 2016	FY 2017
Title: Breast Cancer Center of Excellence	7.907	7.299	0.000

Description: Provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.

FY 2015 Accomplishments:

The Clinical Breast Care Project performed whole genome DNA sequencing on cases of breast cancer; continued development of and support of a robust laboratory information management system to ensure proper tracking of data acquisition and a clinically relevant and laboratory research-linked prospective, database to support translational research and ultimately support physician decision making; continued development of an analytical system for integrative data analysis and mining, and further refined a breast knowledge base to support clinical and research activities in the Breast Cancer CoE; utilized Clinical Laboratory Workflow System as the data analysis tool and integrated Armed Forces Health Longitudinal Technology Application data from the military's main electronic medical record; identified and counseled patients at high risk for development of breast cancer, and employed risk reduction strategies; performed targeted research by conducting DNA and protein analysis of Stages I, II, and III breast cancer, cancer found in the breast ducts and lobules, and pre-malignant breast lesions; and presented findings in peer-reviewed publications and at national meetings.

FY 2016 Plans:

The Clinical Breast Care Project is currently conducting clinical studies to relate genomic and functional heterogeneity (genetic diversity) and metastasis (secondary malignant growths at a distance from a primary cancer site) with breast cancer patient outcomes. The program continues to collect and catalog breast cancer tumors and blood from DoD beneficiaries and include donor consented samples in the Tissue and Blood libraries for analysis. Also conducting studies to determine if there is a correlation between environmental chemical burden and molecular aberrations with breast cancer patient outcomes, as well as conducting human epidermal growth factor receptor 2 (HER2) targeted therapy optimization studies to gain a better understanding

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
of the molecular changes associated with alterations in HER2 expression. Results are leading to a more precise diagnosis and customized treatment plans of patients diagnosed with HER2+ breast cancer. ***FY 2017 Plans:*** No funding programmed. Funding for Breast Cancer Center of Excellence transferred from Army to USUHS starting in FY 2017.			
Accomplishments/Planned Programs Subtotals	7.907	7.299	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 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
378B: *CoE-Breast Cancer Center of Excellence (USU)*	0.000	0.000	0.000	9.900	-	9.900	9.088	10.280	10.475	10.685	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 2015	FY 2016	FY 2017
Title: Breast Cancer Center of Excellence	0.000	0.000	9.900
Description: Breast Cancer CoE provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. ***FY 2015 Accomplishments:*** No funding programmed. ***FY 2016 Plans:*** No funding programmed. ***FY 2017 Plans:*** The Uniformed Services University of the Health Sciences (USUHS) will assume the research oversight of the Breast Cancer Center of Excellence (CoE) beginning 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). Will 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). Will 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. Will use state-or-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.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
The Breast Cancer CoE will 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 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 will be 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.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	9.900

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 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	22.132	6.909	6.377	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 (Army) 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 2015	FY 2016	FY 2017
Title: Gynecological Cancer Center of Excellence (Army)	6.909	6.377	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 2015 Accomplishments:

The Gynecological Cancer Center of Excellence (GYN-COE) conducted retrospective longitudinal and prospective validation studies of biomarker candidates from our previous studies of gynecological cancer early detection, metastasis, recurrence and racial disparities, and new studies of biomarkers and clinical factors associated with patient survival, drug resistance and cancer outcome. These investigations relied on internally collected specimens as well as external collections of annotated biospecimens (materials taken from the human body such as blood, plasma, urine, etc. that can be used for diagnosis and analysis) from the Gynecological Oncology Group (GOG)- trials, the Prostate, Lung, Ovarian and Colorectal (PLCO) trial, and collaborating institutions. Pre-clinical studies examined mechanisms of action, surrogate end points and casual relationships of candidate biomarkers, oncogenes, tumor suppressors and signaling molecules using immortalized and malignant models of human gynecological cancer. The candidates identified in preclinical models were used to design human trials as surrogates/ predictors of response to the chemopreventive (use of biologic or chemical agents to prevent progression of cancer) combination of progesterone/progestin and vitamin D. Hypotheses generated from systems-level integration of molecular studies were evaluated using models of subtypes of ovarian and endometrial cancer. Our previous findings that folate binding protein (FOLR-I) was overexpressed in ovarian and endometrial cancer with others demonstrating that peptides in FOLR-I were highly immunologic resulted in an exploratory safety and effectiveness test in humans of the FOLR_I peptides E39 and J65 with GM-CSF to establish dosing, safety, immunomodulatory activity and prevention of ovarian and endometrial cancer recurrence and death completed accrual with remaining patients receiving vaccine boosters and/or in follow up. The randomized trial to evaluate the effects of a

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
biobehavorial intervention to reduce stress and anxiety versus a monitoring and information intervention on progression-free and survival in ovarian cancer with evaluations of biomarker changes in serial biofluids was developed and opened to accrual. ***FY 2016 Plans:*** The Gynecological Cancer Center of Excellence is conducting both discovery and validation studies of predictive and clinically relevant biomarkers and molecular targets for the treatment and management of ovarian and endometrial cancers, evaluates the effect of stress intervention on the recurrence of ovarian cancer, works 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, performs 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 is developing strategies to overcome chemotherapy drug- and radiation-resistance in gynecologic cancer cells. The program seeks 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 the tumor suppressor genes ARID1A, BRCA1/2 and p53. Additionally we are investigating inhibitors of DNA damage response signaling, specifically the ATR protein kinase (an enzyme with a specific gene), to enhance treatment efficacy of multiple modalities of cancer treatment. The program is developing assays for clinical and cancer biomarkers that have diagnostic, prognostic, predictive and therapeutic value. Specific focus is being given to biomarkers for early detection as well as for prediction of risk of death, disease progression, treatment resistance, and therapeutic response. The program seeks to directly impact clinical care and outcome by furthering our laboratory studies of the therapeutic FOLR-I peptide vaccines, E39 and J65 with GM-CSF developed in collaboration with the COE, as well as clinical trials and window trials evaluating combinations and novel therapeutics in gynecological cancers. Furthermore, chemoprevention efforts focus 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 trial. Inflammatory cytokines, chemokines as well as tumor-derived and circulating biomarkers are being examined in clinical trials and our randomized intervention trial. Robust tissue and data collection continues to support all of our long term research goals and objectives. ***FY 2017 Plans:*** No funding programmed. Funding for Breast Cancer Center of Excellence transferred from Army to USUHS starting in FY 2017.			
Accomplishments/Planned Programs Subtotals	6.909	6.377	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
379B: *CoE-Gynecological Cancer Center of Excellence (USU)*	0.000	0.000	0.000	8.655	-	8.655	7.943	8.987	9.158	9.341	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 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 2015	FY 2016	FY 2017
Title: Gynecological Cancer Center of Excellence	0.000	0.000	8.655

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 2015 Accomplishments:
No Funding Programmed.

FY 2016 Plans:
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, 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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
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 biorespository 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.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	8.655

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	8.496	3.281	3.520	3.051	-	3.051	2.697	2.914	3.118	3.180	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 2015	FY 2016	FY 2017
Title: Integrative Cardiac Health Center of Excellence (Army)	3.281	3.520	3.051
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 2015 Accomplishments: The Integrative Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), conducted research studies initiated in FY 2013-2014. Data collection from approved FY 2013-2014 protocols was analyzed and synthesized. ICHP continued translating and communicating best practices to the services in order to augment existing clinical practice. Utilizing a Knowledge-to-Action framework, ICHP continued incorporating findings from its studies for new hypothesis generation and development of new protocols for FY 2015- 2019 to expand the use of point-of-care technology in the ICHP model. These new protocols were developed to include whole-genome sequencing for early cardiovascular disease (CVD) detection, and investigating the use of serum biomarker maps for personalized CVD risk assessment in Wounded Warriors.			
FY 2016 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
The Integrative Cardiac Health Center of Excellence (Army), ICHP, continues to develop clinical practice guidelines and tools for cardiovascular and overall health, conducts clinical studies to investigate the effectiveness of lifestyle change interventions (nutrition, sleep, stress, and exercise) specifically designed for the Active Duty (AD) population. These studies investigate how lifestyle behavior change can change the negative trajectory of effects on preclinical disease such as atherosclerosis (plaque deposits in artery) measures and pre-diabetes, an atherosclerosis equivalent. ICHP's outcomes-driven research includes biomolecular studies to understand the cardiovascular risk in Wounded Warriors exploring predictive biomarkers (biological indicators of disease) over time. Recruitment is ongoing. ICHP is actively recruiting patients to investigate the effects of the ICHP lifestyle intervention on vascular function in the young military population with high lifetime risk using biomolecular markers for early disease detection. The ICHP cognitive behavioral therapy (CBT) is testing the impact of CBT as a tool to relieve insomnia symptoms (a CVD risk factor for heart attack and common issue in military population) in the ICHP CV Health model. ***FY 2017 Plans:*** The Integrative Cardiac Health Center of Excellence, ICHP, will impact 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 (plaque in arteries). ICHP will continue recruitment in the study to investigate the effects of lifestyle intervention on vascular function in the AD Service members with high lifetime CVD risk but who currently do not have clinical heart disease. ICHP will improve the precision of cardiovascular disease (CVD) risk assessment and detection by exploring novel biomolecular markers and tests as indicators for early disease. ICHP will collaborate with the Mayo Clinic and Cleveland Clinic 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. The Wounded Warriors project will explore 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.			
Accomplishments/Planned Programs Subtotals	3.281	3.520	3.051

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.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 (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 FY15, the Pain CoE funding line is transferred from Army to USUHS.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
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 2015 Accomplishments:*** No funding programmed. Funding transferred to USUHS. ***FY 2016 Plans:*** No funding programmed. Funding transferred to USUHS. ***FY 2017 Plans:*** No funding programmed. Funding transferred to USUHS.			
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: PB 2017 Defense Health Agency		Date: February 2016
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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
382B: *CoE-Pain Center of Excellence (USUHS)*	0.000	2.484	2.823	2.641	-	2.641	2.822	3.310	3.376	3.445	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 2015	FY 2016	FY 2017
Title: Pain Center of Excellence (USUHS)	2.484	2.823	2.641

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 2015 Accomplishments:

The Uniformed Services University of the Health Sciences (USUHS) assumed the research oversight of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) beginning in FY 2015. DVCIPM led MHS effort to formally establish the PASTOR/PROMIS program and the PASTOR Steering Committee within the Defense Health Agency. DVCIPM serves as the ex-officio chair of this Tri-Service Committee that will oversee the enterprise wide roll-out and administration of the PASTOR program. DVCIPM established a REDCap-based research version of PASTOR termed PASTOR Research that supports IRB approved clinical research projects outside of the EMR and offers enhanced patient question flexibility. Federal medicine's PASTOR program is serving as a model for obtaining patient reported outcomes data and was noted as an exemplary program within the recently released NIH National Pain Strategy.

DVCIPM continued to explore pain management therapeutic options to develop and optimize best practice guidelines for the treatment of pain. The research program conducted protocols focused on; evaluation of medications such as Ketamine for improved pain management; clinical studies of integrative medicine modalities such as battlefield acupuncture (BFA) for which1,850 providers have been trained and yoga; and the exploration of the pathophysiology; and molecular mechanisms of pain. DVCIPM continues its role to provide subject matter expertise, coordination, and guidance to the military health system

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
and the Veterans Health Administration regarding pain-related issues and support for implementation of the DoD/VHA Pain Management Task Force Report recommendations. DVCIPM presented a briefing to request designation as a Defense Center of Excellence (DCoE) by the CoE Oversight Board. The CoE Oversight Board members voted to recommend DCoE designation of the DVCIPM to the ASD (HA). ***FY 2016 Plans:*** 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 patient pain registry and biobank. The registry will be leveraged through 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; acupuncture yoga and massage; evaluation of novel analgesics; and interventional technologies for improved pain management. DVCIPM will continue to serve as the MHS's coordinating organization for pain education and clinical policy development, critical to the continued transformation of DoD pain management. ***FY 2017 Plans:*** 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.			
Accomplishments/Planned Programs Subtotals	2.484	2.823	2.641

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	21.287	6.303	6.260	7.900	-	7.900	7.250	8.203	8.359	8.526	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Uniformed Services University of the Health Sciences' (USUHS), Prostate Cancer Center of Excellence (CoE), formerly a Congressionally enacted program (Public Law 102-172 1991) was chartered to conduct state-of-the-art clinical and translational research with emphasis on precision medicine. In essence, the goal is 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. The program's mission is fulfilled primarily through its three principal programs-the Clinical Translational Research, the Basic Science Research and the Tri-Service Multicenter Database which includes five participating military medical centers. The CPDR has been conducting patient centric cutting - edge translational research to improve the management of all stages of prostate cancer for over 23 years as recognized by nearly 450 scientific publications. The CPDR is also committed to the research training of the next generation of DoD physicians and scientists (USU medical /graduate students and Walter Reed/USU residents). Many of the trainees are now service chiefs and program directors in prestigious military and civilian medical centers

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: CoE-Prostate Cancer Center of Excellence (USUHS)	6.303	6.260	7.900
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.			
FY 2015 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Precision Medicine Research Focus: • First evaluations of the MRI-ultrasound fusion image guided biopsy in a DoD medical center (at Walter Reed, Bethesda). • Validation of a new biopsy-based 17-gene Genomic Prostate Score (Oncotype DX Prostate Cancer Test) in a racially diverse DoD prostate cancer patient population. Health Disparity Research: • CPDR led world-wide collaborations reveal striking ethnic differences of the most common prostate cancer driver gene, ERG. • Prostate cancer genome evaluation of African American patients led to ground-breaking discovery of a prevalent gene defect in aggressive prostate cancers. CPDR has recently published this discovery reporting a first high frequency genomic deletion in aggressive prostate cancers of African Americans (Petrovics et al, E-Biomedicine online version Nov 8, 2015 [supported by Cell Press and Lancet]; Commentary by Zhaoming Wang, EBiomedicine on line version, Nov 24, 2015). This discovery has potential to impact future care of African American prostate cancer patients within the MHS and civilian setting. Development of Molecular Diagnostic and Prognostic Tools: • Streamlined evaluation of ERG defects in prostate cancer led by CPDR ERG-MAb continues to open new opportunities (leading researchers of the prostate cancer field) in improving prostate cancer diagnosis and prognosis. Novel Strategies for Androgen Receptor Targeted Stratification and Treatment: • Continued evaluation of a CPDR androgen receptor function index (ARFI) gene panel further supports a new sub-type of prostate cancers with attenuated androgen signaling emerging during the progression from hormone-naïve to castration-resistant prostate cancer. The CPDR Education and Training program: • Three urology residents from WRNMMC and five USU medical students completed the translation research training at CPDR.			
FY 2016 Plans: Clinical Research Focusing on Precise Diagnosis and Therapy: •Assess new FDA approved therapies; e.g., Enzalutamide, Abiraterone Acetate, Provenge and Radium-223, and vaccine therapy therapies. •Evaluate the newest aspects for prostate biopsy procedure using MRI-ultrasound fusion image technology for improving diagnosis of clinically significant cancer. •Leverage the vision of long-term biospecimens and database for timely collaborative studies, complete the collaborative validation study of the Oncotype DX-Prostate Cancer prognostic panel to differentiate indolent prostate cancers from the aggressive disease. •Develop more accurate prognostic models to predict organ-confined (curable) and outcome (survival) after the above-noted treatments. •Conduct long-term comparisons of efficacy, morbidity, mortality and quality-of-life impact for accepted and emerging treatments for early stage prostate cancer.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
•Conduct a long-term study of the epidemiology of prostate cancer, to include the tracking of changing stage, age at diagnosis, racial makeup, long-term survival, and quality-of-life-adjusted survival. CPDR Tri-Service National Database Operations: •Build clinical models for predicting probability of prostate cancer detection in the diagnosis phase, optimal treatment decision in the treatment phase, and outcome based treatment in the follow-up phase. •Integrate clinical and molecular biomarker prognostic variables for evaluating patient diagnosis, progression, and treatment outcomes. •Facilitate collaborations between basic science research and clinical research at the CPDR and other institutions. •Support translational research at WRNMMC where clinical data are linked to tissue and serum data banks to support molecular genetic studies. •Provide a resource for education/training of urology, radiation oncology, medical oncology and other residents, fellows, and students. Biospecimen Banking Effort: •Leverage the unique whole mounted prostate specimen bank with long post-treatment follow up for the identification of early prognostic markers of indolent or progressive disease. •Complete validation of Oncotype DX® Prostate Cancer prognostic assay with Genomic Health, Inc. to distinguish between indolent and aggressive prostate cancer utilizing diagnostic biopsy specimens. •Support our major new initiative of CaP genome analysis in African American patients by NextGen sequencing technologies. •Complete the translation of the new post-DRE urine assay developed at CPDR for the detection of prostate cancer by immune-cytochemistry based platform. •Enhance DOD, Government and other academic collaborations assessing the association of BRCA1&2 mutations in aggressive CaP and defining the genetic determinants of African American prostate cancer. •Maintain Bio-Medical Informatics Core to support the current information systems requirements of the CPDR programs. New Biomarker and Therapeutic Target Discoveries: •Continue to build on new molecular strategies at the CPDR for improving prostate cancer diagnosis and prognosis. •Leverage new promising data on molecular differences of cancer gene defects between African American and Caucasian American prostate cancer patients towards enhancing personalized medicine in diverse population represented in DOD equal access healthcare system. •Continue to enhance the clinical utility of the CPDR-ERG monoclonal antibody (100% specific for prostate cancer detection) based new strategies of biological stratification and treatment of prostate cancer with in DoD and civilian setting. •Develop and evaluate novel molecular therapeutic agents for early detected cancer targeting the most common ERG positive prostate cancer with potential in leading to paradigm shift in new generation of prostate cancer therapeutics. •Continue to define genetic and molecular determinants of prostate cancer in high-risk groups focusing on African-American men. •Evaluate cancer biology of prostate cancer relevant genes or proteins using established and new experimental models.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
•Continue to enhance hormonal mechanisms for more precise and effective therapeutic stratification of prostate cancers treated by androgen ablation therapies. •Leverage the CPDR discovery platforms for frequent and potentially causal prostate cancer gene alterations using cutting edge technologies and well annotated and precisely processed bio-specimens. Education and Training Program: •Foster education and training in prostate cancer basic science and translational research and provide opportunities for post-doctoral fellows, residents, visiting scientists, medical and graduate students and summer interns. •Utilize the CPDR developed structured molecular oncology training program in prostate cancer for physician and scientists. •Invite leading experts in prostate cancer field to give state-of-the-art lectures as a part of education and training of post-doctoral fellows, residents, graduate students and research staff. •Sponsor research investigator programs for DOD physicians and scientists on prostate cancer research diagnosis, treatment and therapeutic advances. •Collaborate with other DOD, government, and private agencies in promoting and sponsoring prostate disease research education. Material and Knowledge Products - Continue to: •Support new knowledge products through in-house initiatives and collaborative efforts with leading medical institutions and biotechnology companies. •Leverage the largest (27,500+ subjects) and long term (22+ years) multi-center CPDR database within the DOD for developing more precise diagnostic and prognostic biomarkers and nomograms towards enhancing personalized medicine with special focus on ethnically diverse patient population within the DOD. •Enhance CPDR Biospecimen Bank which is considered to be a national treasure for new discoveries of prostate cancer biomarkers and therapy targets. •Leverage the growing intellectual property portfolio of USU-CPDR for developing innovative diagnostic and therapeutic products and technologies to enhance the care of prostate cancer patients within the MHS.			
FY 2017 Plans: Precision Medicine Focus: • Continue to focus on studies addressing the utility of MRI-ultrasound fusion image technology for improving diagnosis of clinically significant cancers. • Further enhance the collaborative validation study of novel prognostic and diagnostic biomarker panels. • Continue to leverage the unique DoD prostate cancer research resource integration of clinical, biospecimen and molecular databases through advanced informatics platforms.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
• Conduct long-term comparisons of efficacy, morbidity, mortality and quality-of-life impact for accepted and emerging treatments for early stage prostate cancer leading to more accurate prognostic models to predict organ-confined (curable) and outcome (survival) following treatments. Health Disparity Research: • Leverage CPDR's lead towards identification of genes that will enhance diagnosis, prognosis and treatment of ethnically diverse prostate cancer patients in MHS. • Develop alliance with USU/CHIRP initiative 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). New Therapeutic Targets in Prostate Cancer: • Accelerate the pre-clinical development of the novel therapeutic inhibitors of ERG, such as, USU-ERGi for early detected cancer with promise for a paradigm shift in new generation of prostate cancer therapeutics. Development of Molecular Diagnostic and Prognostic Tools: • Continue to enhance the prognostic utility of the CPDR-ERG monoclonal antibody in the context of ethnicity. • Accelerate the development of the cost-effective CPDR UCAP assay for urine-based detection of prostate cancer. • Leverage the discovery of prognostic biomarker candidates from whole-genome and whole-transcriptome analyses for defining an ethnicity-informed prognostic panel for prostate cancer. Novel Strategies for Androgen Receptor Targeted Stratification and Treatment: • Continue to develop novel concepts in facilitating degradation of androgen receptor, a central player in development of castration resistant prostate cancer. Develop small molecules to facilitate AR protein degradation. Education and Training Program: • Continue to utilize the CPDR developed structured training programs for fostering education and training of next generation of military physicians and scientists in state-of-the-art translational research. Material and Knowledge Products: Material products: • Biospecimen Bank (230,000 units of various types of molecular and clinical specimens linked to longitudinal follow up since 1993). • ERG monoclonal antibody for the diagnosis of prostate cancer (in clinical use, Biocare Medical Inc.). • OncotypeDX Prostate Cancer – biopsy based prognostic genomic assay validation (in clinical use, Genomic Health Inc.). • ERG inhibitor (ERGi-USU) for therapeutics (patent application) Knowledge products: • CPDR National Database 28000+ subjects with longitudinal follow up (up to 1,000 data fields/patient) a resource for biomarker discovery and therapeutic outcome studies. • Discovery of genetic and genomic prognostic biomarkers of prostate cancer (patent application).			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
• Gene panel for the detection of prostate cancer (patent application).			
Accomplishments/Planned Programs Subtotals	6.303	6.260	7.900

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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	-	-

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 2015	FY 2016	FY 2017
Title: CoE-Neuroscience Center of Excellence (USUHS)	0.000	0.000	0.000
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 2015 Accomplishments:*** None, MCNCoE research has been merged into the CNRM beginning in FY 2015. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 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: PB 2017 Defense Health Agency		Date: February 2016
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)*

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 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: PB 2017 Defense Health Agency		Date: February 2016
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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
431A: *Underbody Blast Testing (Army)*	31.867	4.397	2.679	1.869	-	1.869	0.000	0.000	0.000	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), the Underbody Blast (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 2015	FY 2016	FY 2017
Title: Underbody Blast Testing	4.397	2.679	1.869

Description: Will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or IED, and will provide 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 live-fire test and evaluation (LFT&E) crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats.

FY 2015 Accomplishments:

The Underbody Blast Testing project continued medical research in the areas initiated in FY 2014 but with the emphasis shifting during the year from non-injurious conditions to those which cause injuries. This enabled the development of initial human injury probability curves that account for influences unique to the military and to the underbody blast environment. All data transitioned into the Warrior Injury Assessment Manikin (WIAMan) project to enable the fabrication of the first and second generation prototype anthropomorphic test devices (ATDs; manikins or crash test dummies). Validation studies contrasted injuries observed in theater

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
with those created in the testing program to prioritize further research. Emerging medical research data supported the protection technology development and the modeling and simulation initiatives. ***FY 2016 Plans:*** The Underbody Blast Testing project is continuing 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 is enabling 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 is informing the development of whole-body and component injury criteria and the protective technology for use in the underbody blast environment. ***FY 2017 Plans:*** Will continue to develop body region specific injury criteria under blast loading using whole body dynamic data from whole body blast tests. Various hypotheses will be tested to determine how to create the first injury (i.e., fracture) and subsequent severe injuries (i.e., complex fractures). The goal will be to predict injury with enough resolution to make decisions between competing protective equipment. Supported hypotheses from preliminary component testing will be used in finalized tests to generate and update human injury probability (dose-response) curves and injury assessment response curves (cadaver - ATD relationship).			
Accomplishments/Planned Programs Subtotals	4.397	2.679	1.869

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Produce biofidelity response corridors (BRC) and human injury probability curves (HIPC) for human skeletal response and tolerance in the military UBB environment and transition them for use in the development of the WIAMan UBB test manikin and for general use in the RDT&E community. Develop injury assessment reference curves for use with WIAMan manikin to support vehicle and protection technology acquisition decisions.

E. Performance Metrics

Performance metrics include the timely transition of actionable medical research from principal investigators for use in the development of the WIAMan UBB test manikin and to benefit the RDT&E protection technology and acquisition community. Actionable medical research includes biofidelity response corridors (BRCs), human injury probability curves (HIPC), and injury assessment reference curves (IARCs). Principal investigators (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 Program Sponsor Representative

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 431A / *Underbody Blast Testing (Army)*

progress review 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
448A: *Military HIV Research Program (Army)*	6.663	5.270	6.589	6.070	-	6.070	6.359	7.360	7.877	8.035	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project funds research 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. All HIV technology development is conducted in compliance with US 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 drug, vaccine, or device for the targeted disease or condition in a small study; and third, to demonstrate effectiveness in large, diverse human population 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 the next phase of development for completion of effectiveness testing in larger populations. This program is jointly managed through an Interagency Agreement between USAMRMC and the National Institute of Allergy and Infectious Diseases (NIAID). 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 2015	FY 2016	FY 2017
Title: Military HIV Research Program	5.270	6.589	6.070
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.			
FY 2015 Accomplishments: Conducted initial testing in humans for safety and effectiveness at CONUS and OCONUS sites with down-selected HIV-1 multivalent vaccine candidates, either a single vaccine or a combination of several sub-types. Prepared methods for large scale production of vaccine candidates from various world-wide subtypes. These candidates are being used in future large scale clinical studies.			
FY 2016 Plans: Complete large scale production and characterization of selected vaccine candidates. Initiate large scale safety and effectiveness trials with one or more vaccine candidates either as single vaccine or combination of several sub-types representing major world-wide distribution.			
FY 2017 Plans: Will perform 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-risk volunteers. Will initiate a human population study that will provide knowledge about the earliest HIV events to provide possible clues in developing an			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
effective HIV vaccine or help identify ways to achieve a functional cure. Will test extended safety/dosing/immunogenicity studies with the best combination vaccine candidate.			
Accomplishments/Planned Programs Subtotals	5.270	6.589	6.070

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 are 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 (IIPT) and in-process reviews (IPR).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
830A: *Deployed Warfighter Protection (Army)*	14.226	4.156	5.306	4.889	-	4.889	5.123	5.930	6.345	6.472	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Armed Forces Pest Management Board (AFPMB), the Deployed Warfighter Protection project plans to develop new or improved protection for ground forces from disease-carrying insects. The focus of this program is to develop new or improved systems for controlling insects that transmit malaria, dengue, chikungunya and other emerging infectious diseases 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 President's Malaria Initiative and the WHO Global Malaria Program to lead development of new tools for insect-borne disease prevention.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Deployed Warfighter Protection	4.156	5.306	4.889
Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects.			
FY 2015 Accomplishments: The Deployed Warfighter Protection (DWFP) research program focused research efforts on critical gaps identified by the Services and Combatant Commands to control insect disease vectors to provide solutions in three thrust areas: personal protection systems, new insecticides, and vector control/insecticide application technologies. Within the enhanced personal protection systems, DWFP evaluated the feasibility of bite-proof fabrics, studied the durability of factory permethrin-treated uniforms, and searched for a replacement insecticide that safely outperforms the current treated uniforms. Regarding spatial repellents, the DWFP down-selected and evaluated a chemical to augment the use of personal topical repellents, such as DEET, which require frequent application, suffer from low levels of user acceptability, and are short lived (lasting only hours). Such a spatial repellent promises to protect personnel when not in uniform and when DEET or other skin repellents are not used. Conducted early field tests of prototype passive area/spatial-repellent dispensers; and conducted a preregistration meeting with the parent commercial company and the EPA to determine steps required for regulatory approval of the repellent in the US. To counter the rising problem of mosquito resistance to existing insecticides and the issue of currently approved insecticides being removed due to more stringent regulatory requirements, focused on developing the next generation of insecticides which will be more effective at protecting deployed personnel while also being safer for humans and the environment. The DWFP collaborated with multiple industry partners to develop such new insecticides for EPA registration. For vector control technologies, targeted pesticide delivery methods that are more effective, efficient, and sustainable in austere and tropical environments. In addition to materiel solutions/			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
products, DWFP priorities included knowledge products that support vector control and disease risk reduction to include improving current practices used in the field. ***FY 2016 Plans:*** In FY 2016 the Deployed Warfighter Protection (DWFP) research project is developing tools that enable deployed forces to better protect themselves and control biting insects, primarily mosquitoes and sand flies, which transmit force degrading diseases. This is being accomplished through research, testing and evaluation of products, patent submissions, licensing, and EPA registrations for new insecticides. The DWFP is maintaining its focus on personal protection systems, new insecticides, and vector control/insecticide application technologies. For enhanced personal protection systems, protective clothing efforts are being 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 is being completed and, if effective, will be submitted to the Armed Forces Pest Management Board (AFPMB) and the EPA for approval and registration. Within this same focus area, under area/spatial repellents, the DWFP is expanding field tests focused on the best performing area/spatial-repellent dispensers evaluated in FY 2015 and is working with the EPA and associated industry partner to pursue EPA registration for military use. For new insecticides, the DWFP is down selecting top performing novel molecular pesticides tested in FY 2015 for expanded field testing; conducting faster, more efficient, lab based screening of potential plant-derived and synthetic insecticides to identify promising candidate compounds; and is executing field evaluations of insecticides identified in FY 2015. For vector control/insecticide application technologies, lab and field testing of insecticide sprayer products identified as promising tools in FY 2015 are being conducted with a focus on remotely operated and/or autonomous spraying capabilities. Best performing products/sprayers and technologies tested in FY 2015 are transitioning to industry partners for commercialization and submission to the AFPMB for addition to the National Stock System. ***FY 2017 Plans:*** In FY 2017 the Deployed Warfighter Protection (DWFP) research project will lead 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 and sand flies, which transmit force degrading diseases. This will be accomplished through research, testing and evaluation of products, patent submissions, licensing, and EPA registrations for new insecticides and bite protection tools. The DWFP will 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) will be patented and will transition to the US 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 will transition 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 will drive commercialization strategies and licensing agreements for fielding an area/spatial-repellent device to provide passive protection from mosquito biting. In the insecticides development portfolio, the exploration of natural/biopesticides with improved environmental and human safety profiles			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
will continue. Molecular pesticide development and testing partnerships with two major global insecticide developers will continue. Field evaluation of first generation, species-specific molecular insecticides targeting mosquitoes will start; following completion of the AFPMB led Vector Control Capabilities Gap Analysis, the AFPMB pesticides committee will identify priority insecticide gaps, which will drive FY 2017 funding for pesticides-related R&D. For vector control/insecticide application technologies, a new silent backpack sprayer developed by DWFP, licensed by industry in FY 2015 and improved by the commercial partner in FY 2016 will be commercially available. New technology to enable remotely operated and/or autonomous insecticide application will be explored. Partners will add data to two vector control mobile apps which serve as decision support tools for deployed entomologists. Technology developed will provide solutions to prevent malaria needed by the President's Malaria Initiative and partners in the WHO Global Malaria Program.			
Accomplishments/Planned Programs Subtotals	4.156	5.306	4.889

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 US forces from disease-carrying insects. 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 and relevant Program Executive Offices (PEOs) to transition efforts.

E. Performance Metrics

Performance for the Deployed Warfighter Protection 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-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
Total Program Element	648.887	146.411	175.518	96.602	-	96.602	114.382	131.866	143.793	148.111	Continuing	Continuing
374A: *GDF-Medical Products Support and Advanced Concept Development*	525.045	85.628	99.443	92.602	-	92.602	110.382	127.866	139.793	144.031	Continuing	Continuing
400Z: *CSI - Congressional Special Interests*	116.933	60.783	72.075	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	0.000	4.000	4.000	-	4.000	4.000	4.000	4.000	4.080	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force (GDF) - 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, 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 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, 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, 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 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: PB 2017 Defense Health Agency	Date: February 2016
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 DHP Congressional Special Interest (CSI) research funding focused on Peer-Reviewed Traumatic Brain Injury/Psychological Health, Joint Warfighter Medical Research, and Restore Core Research Funding Reduction. The Uniformed Services University of the Health Sciences received CSI funding for the Therapeutic Service Dog Training Program. 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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	97.787	103.443	129.137	-	129.137
Current President's Budget	146.411	175.518	96.602	-	96.602
Total Adjustments	48.624	72.075	-32.535	-	-32.535
• Congressional General Reductions	-0.173	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	60.783	72.075			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-3.463	-			
• SBIR/STTR Transfer	-8.523	-			
• Rebalance Joint Program Committees	-	-	-13.403	-	-13.403
• DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-9.738	-	-9.738
• Health Information Technology Optimization Reduction	-	-	-7.000	-	-7.000
• Restore USUHS Breast, GYN, and Prostate Cancer Centers of Excellence	-	-	-2.394	-	-2.394

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Project: 400Z: *CSI - Congressional Special Interests*		
Congressional Add: *427A - Traumatic Brain Injury / Psychological Health*	20.000	21.375

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Congressional Add: *441A - Joint Warfighter Medical Research Program*	20.000	20.000
Congressional Add: *455A - Therapeutic Service Dog Training Program (USUHS)*	3.000	0.000
Congressional Add: *464A – Program Increase: Restore Core Research Funding Reduction (GDF)*	17.783	30.700
Congressional Add Subtotals for Project: 400Z	60.783	72.075
Congressional Add Totals for all Projects	60.783	72.075

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0604110-Medical Products Support and Advanced Concept Development (-$8.523 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$8.523 million).

FY 2015: Federally Funded Research and Development Center (FFRDC) Reduction (FFRDC), PE 0604110-Medical Products Support and Advanced Concept Development (-$0.173 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+ $60.783 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).

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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*

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).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
374A: *GDF-Medical Products Support and Advanced Concept Development*	525.045	85.628	99.443	92.602	-	92.602	110.382	127.866	139.793	144.031	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force (GDF)-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- Medical simulation and information sciences. This 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. Initial candidates will be selected from those funded by medical research sponsors in the Department of Defense, and from external sources such as academia and industry, including efforts funded with prior year Congressional Special Interest funding. 2- Military infectious diseases. This 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- Military operational medicine. This 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. This JPC supports clinical trials such as those assessing biomarkers (biological indicators) for traumatic brain injury, and advanced product development related to hemorrhage, extremity trauma, prehospital combat casualty care, and enroute care. 5- Clinical and rehabilitative medicine supports clinical trials related to pain management and regenerative medicine.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: GDF – Medical Product Support and Advanced Concept Development	85.628	99.443	92.602
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 2015 Accomplishments: Medical simulation and information sciences conducted research in two primary research tasks -- medical simulation and health information technology (IT). Under the medical simulation task: Began development on Phase 1 of the Advanced Modular Manikin, a training platform for medical intervention procedures. Phase 1 consists of the development of a core (torso) portion,			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
which will be used in identifying the mechanical requirements for future peripheral development. In addition, developed a direct observation and automated assessment tool for multiple-casualty scenarios that augments human observations with other measurable parameters. Under the health IT task: Continued coordination on electronic medical information technology research to Warfighter care and mitigate program risk for the Military Health System. Identified options to reduce potential near- and long-term risks associated with IT development and legacy systems, and prepared for the transition to the Department of Defense modernized Electronic Health Record. Research continued on closing gaps related to mobile health and personal health management, and advancing the ability to capture data from the point of injury to the point of definitive care. This effort involved data transmission initiatives, new clinical decision support algorithms, and patient identification issues incorporating patient consent, privacy, and security. Military infectious diseases performed initial optimization of polymerase chain reaction-based assays for malaria, dengue, and chikungunya to be used on the Next Generation Diagnostic System for Combat Support Hospitals. Supported clinical study on skin and soft tissue infection in military trainees at Fort Benning, Georgia. Military operational medicine applied the results of clinical trials to the development of clinical practice guidelines for improved psychotherapies (psychological treatment of mental disorders) for the treatment of post-traumatic stress disorder (PTSD). Continued Veterans Affairs-DoD clinical trials studying the use of pharmaceuticals for the treatment of deployment-related symptoms of PTSD (e.g., improving sleep, reducing nightmares). Continued clinical trials examining the efficacy of a program designed to support families throughout the deployment lifecycle and promote positive behavioral health outcomes. Continued development of an objective, blood-based biomarker assay for PTSD screening. Initiated a multi-service clinical trial for validation of daily psychotherapy sessions for (compressed schedule) PTSD treatment, preliminary to knowledge product dissemination. Validated data from human studies on nutrition and dietary supplements. Continued integration of actionable algorithms into physiologic status monitoring systems based on end-user feedback from field studies. Completed a phase II clinical trial of a potential pharmaceutical intervention for hearing loss and tinnitus in a military training environment. Completed development of a new active and passive hearing protection device that increases situational awareness while reducing risk of injury from impulse noise. Combat casualty care. Hemorrhage: Continued safety study in humans that supported FDA Biologic License Application for a spray-dried plasma product. Supported studies on the prehospital use of plasma for treating patients with traumatic hemorrhage. Initiated clinical studies on the use of tranexamic acid, a drug to help control severe bleeding. Supported clinical trials on a device killing infectious organisms in fresh whole blood collected on the battlefield for transfusion. Neurotrauma: Completed assessment of a Burr Hole Trainer prototype instruct on the proper technique for drilling a cranial burr to relieve intracranial pressure. Assessed the effectiveness of non-invasive neuroassessment devices/tools for detecting mild TBI. Evaluated two			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017

traumatic brain injury (TBI) biomarker point-of-care devices in conjunction with a biomarker-specific diagnostic assay system. Continued to develop the Biomarker Assessment for Neurotrauma Diagnosis and Improved Triage System) diagnostic. Supported clinical trials on the Portable Neuromodulation Stimulator as a treatment for mild TBI-associated balance disorders. Continued testing/validation and system refinement of the smooth pursuit eye tracking device for the detection of mild TBI. Continued safety, effectiveness, and dose studies of NNZ-2566 in patients with moderate to severe TBI and began enrollment of mildly affected subjects. Pre-hospital and Enroute Care: Advanced the development of a communication/ data transfer system to provide advanced intensive care capabilities to first responders and frontline Military Treatment Facilities.

Clinical and rehabilitative medicine continued clinical trials for regenerative medicine-based approaches for restoration of limb (arms and legs) and digit (fingers, thumbs and toes) salvage. Transitioned management of Sufentanil Nanotab, a battlefield pain management product, to the Advanced Developer to initiate Phase 3 FDA-regulated clinical trials.

Solicited applications for tri-Service translational research at Military Treatment Facilities with awards pending. Applications were requested to focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, clinical and rehabilitative medicine, and/or health services research including health care informatics, and interventional studies regarding access to care and health care disparities.

FY 2016 Plans:

Medical simulation and information sciences conducts research in two primary research tasks -- medical simulation and health information technology (IT). Under the medical simulation task: Continue the Advanced Modular Manikin Phase 1 development effort, a core (torso) portion for use in the training of medical intervention procedures. In addition, assess the value of stress inoculation simulation training methodologies, technologies, and techniques to protect Warfighters from deployment related psychological stresses and trauma. Conduct a preliminary assessment of a 3-D printer and/or fabricating synthetic material fibers to simulate ophthalmic tissues. Under the health IT task: Continue efforts towards filling theater information technology research gaps such as capturing and transmitting point of injury data, transitioning theater health information into Department of Defense and Veterans Affairs health systems, and resolving technology issues related to a theater environment.

Military infectious diseases continue optimization on the malaria, dengue, and chikungunya infectious disease polymerase chain reaction-based assay panel to be used on the Next Generation Diagnostic System. Continue to support skin and soft tissue infection clinical study in military trainees at Fort Benning, Georgia. These studies are in alignment with National Strategy for Combating Antibiotic Resistance.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Military operational medicine continues the development and validation of lower extremity injury risk prediction models targeted towards quantifying fitness for duty in military training and operational populations, the evaluation of biofeedback sensors as tools to validate injury models, and mobile technology designed to reduce lower back pain in the military. Collaborate with Defense Center of Excellence (DCoE) to develop clinical practice guidelines for improved psychotherapies (psychological treatment of mental disorders) for post-traumatic stress disorder (PTSD), for 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. Complete a study evaluating the efficacy of an intervention designed to support families and Service members throughout the deployment lifecycle. Continue development of an objective, blood-based PTSD biomarker assay through Advanced Development. Continue advanced development of pharmaceutical interventions for hearing loss and tinnitus. Continue studies to validate clinical protocols for the use of nutritional strategies and dietary supplements and confirm safety and efficacy. Develop gender-specific and gender-neutral standards that apply across garrison and combat operations to reduce injuries in the total force. Support the refinement of algorithms to reliably predict core body temperature and estimate physiological work strain from real-time non-invasive measurements (e.g., skin temperature and heart rate) into a physiological health status monitoring system for the end user. Combat casualty care. Hemorrhage: Complete safety study in humans that support FDA Biologic License Application for a spray-dried plasma product and initiate preparation for a larger safety and effectiveness study. Continue clinical studies on the pre-hospital use of plasma for treatment of patients with traumatic hemorrhage. Continue clinical studies on the use of tranexamic acid, a drug to help control severe bleeding. Continue clinical trials and analyze data on a device killing infectious organisms in fresh whole collected on the battlefield for transfusion. Begin clinical trials on an intracavitary hemostatic product to control bleeding (Wound Stasis System). Transition valproic acid, a drug that has demonstrated the potential to prolong patient survival following severe hemorrhage, from the Navy science and technology program into advanced development; ; ; continue initial safety studies in normal volunteers and begin effectiveness studies in patients. Transition 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 advanced development and begin preparation for clinical trials. Start clinical studies in the use of extended shelf life platelets for transfusion.. Neurotrauma: Continue studies advancing the development novel TBI diagnostics. Continue the advanced development of novel diagnostics for mild TBI; begin clinical trials on a point-of-care tool for diagnosing TBI in conjunction with the validation of a biomarker specific assay system. Validate pivotal clinical trial results from the Portable Neuromodulation Stimulator (PONS) as a treatment for mild TBI-associated balance disorders. Perform interim data analysis of the smooth pursuit eye tracking device for the detection of mild TBI and continue to recruit subjects. Finish recruitment and patient follow-up of safety, effectiveness, and dose studies of NNZ-2566 in patients with moderate to severe TBI, analyze data, and prepare final report. Continue recruitment of mildly affected TBI subjects for of safety, effectiveness, and dose trials of NNZ-2566. Continue to develop a clinically useful classification system for TBI, across the spectrum of severity. Begin research to			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
fill knowledge gaps in the treatment of casualties with moderate to severe TBI from the point of injury and during transport, in order to mitigate the progression of TBI and secondary brain injury. Forward Surgical and Critical Care and Enroute Care is advancing the development of a system to provide advanced intensive care capabilities, and data collection systems for battlefield point of injury, mainly in the field of decision assist tools using a physiological opened loop system. Treatments for Tissue Injury continues 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 initiates clinical trials to support evidence-based use of FDA-approved drugs to eliminate heterotopic ossification, a process by which bone tissue forms outside the skeleton. Support Phase 3 FDA-regulated clinical trial enrollment for Sufentanil Nanotab, a battlefield pain management product, and submit a New Drug Application to the FDA. Start FY 2015 tri-Service translational research studies at Military Treatment Facilities recommended for funding to include the recruitment, screening, and enrollment of patients. These efforts focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, clinical and rehabilitative medicine, and/or health services research. ***FY 2017 Plans:*** Medical simulation and information sciences will conduct research in two primary research tasks: Medical Simulation and Health Information Technology (IT). Under the Medical Simulation task: Will initiate studies to optimize individual learning/optimal timing of an individual's insertion into military medical teams in order to improve the quality of care and patient safety. Will evaluate current augmented reality (AR) capabilities, assess AR capability gaps related to military medical applications as compared to current industry practices, and explore anticipated future AR needs. Under the Health IT task: Will implement options to reduce risk associated with the modernization of existing Military Health System legacy systems in support of Healthcare Management System Modernization Electronic Health Record implementation and future integrated MHS applications. Will prototype, test, and support 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 to improve quality of care and patient safety. Will incorporate Theater Operational Medicine health information into Department of Defense and Veterans Affairs global health systems to support the Precision Medicine Initiative. Military infectious diseases will complete optimization and prepare for clinical validation of infectious disease (malaria, dengue, chikungunya) polymerase chain reaction-based assay panel to be used on the Next Generation Diagnostic System. Will complete skin and soft tissue infection clinical study in military trainees at Fort Benning, GA, and apply results towards the prevention and treatment of skin and soft tissue infections. Will test and evaluate promising antibacterials, solicit proposals focused on advanced development of antibacterials. These studies will support the National Strategy for Combating Antibiotic Resistance.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Military operational medicine will validate lower extremity injury models using biofeedback sensors. Will complete a study testing the efficacy of omega-3 supplementation to prevent and/or reduce suicide behaviors. Will conduct clinical studies to evaluate the association between diet composition and health status. Will perform studies to evaluate the efficacy of a dietary intervention to improve Warfighters' omega-3 fatty acid status in a garrison feeding environment. Will begin to conduct studies aimed at optimizing suicide prevention interventions. Will continue objective, blood-based PTSD biomarker screening assay development with an industry partner. Will initiate psychopharmacologic study(s) via a RFP process following State-of-the-Science for PTSD Psychopharmacologic Intervention Target meeting to be held in late spring of 2016. Will begin to evaluate nutritional and other interventions that may prevent and/or minimize musculoskeletal injury in female Warfighters. Will transition 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. Will continue to test and refine algorithms to be embedded into the physiologic status monitor system that will provide actionable physiological health status information in real-time to the Service member and unit leader. Will begin Phase III clinical trials of pharmaceutical interventions for hearing loss and tinnitus. Combat casualty care. Hemorrhage: Will initiate safety, effectiveness, and dose studies supporting FDA Biologic License Application for a spray-dried plasma product. Will complete the clinical studies on the pre-hospital use of plasma for traumatic hemorrhage. Will complete clinical studies on the use of tranexamic acid, a drug to help control severe bleeding. Will continue clinical trials on an intracavitary hemostatic product to control bleeding (Wound Stasis System). Will complete safety/initial effectiveness studies in humans, and will continue safety, effectiveness, and dose studies on valproic acid as part of an assessment of its ability to prolong patient survival after severe hemorrhage. Will complete safety/initial effectiveness studies in humans using Ethinyl Estradiol 3 sulfate, a drug for low volume resuscitation of patients with hemorrhagic shock following severe bleeding after trauma, and support ongoing clinical trials assessing the ability of similar low volume resuscitation drugs. Will continue clinical trial to extend the shelf life of platelets in theatre. Neurotrauma: will pursue studies advancing the development of traumatic brain injury (TBI) biomarker detection tools with primary objective of monitoring progression of injury condition with treatment. Will continue clinical trials on a point-of-care tool for diagnosing TBI in conjunction with the validation of a bio-marker specific assay system and downselect one device for use in the forward operating environment. Will complete recruitment of mildly affected TBI subjects for of safety, effectiveness, and dose trials of NNZ-2566, analyze results, and prepare final report. Will identify and clinically relevant TBI endpoints, across the spectrum of injury severity, to support regulatory approvals and applicability for use in research tests and clinical trials with the ultimate goal of improving clinical trial design and accelerating FDA approval. Continue studies to advance knowledge of treatment and management of casualties with moderate to severe TBI from the point of injury and during transport in order to mitigate the progression of TBI and secondary brain injury. Forward Surgical and Critical Care and Enroute Care will advance a system to provide advanced intensive care capabilities such as the implementation of automated systems to enroute care clinicians to include an understanding of the appropriate provider skill levels involved and			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
the impact on patient outcomes. Will start testing decision assist tools using a physiological closed loop system. Specifically, an intravenous anesthesia closed loop device will be moving through the FDA approval process in the next 3-5 years. Treatments for Tissue Injury will continue 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 will continue efforts in the areas of military-relevant pain management and regenerative medicine. Complete Phase 3 FDA-regulated clinical trials for Sufentanil Nanotab, a battlefield pain management product. Implement inter-agency clinical trials on individualized (precision medicine), integrative pain management for Wounded Warriors. Continue FY 2015 efforts, and begin FY 2016 tri-Service translational research studies at Military Treatment Facilities 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, and/or health services research.			
Accomplishments/Planned Programs Subtotals	85.628	99.443	92.602

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 Food and Drug Administration approval and Environmental Protection Agency registration.

E. Performance Metrics

Research is evaluated through In-Progress Reviews, DHP-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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
400Z: *CSI - Congressional Special Interests*	116.933	60.783	72.075	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2015 DHP 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 2015	FY 2016
Congressional Add: 427A - Traumatic Brain Injury / Psychological Health	20.000	21.375
FY 2015 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest research program aims 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 TBI/PH research program are to support projects aligned with the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service members, and Military Families; address Congressional intent; enable significant research collaborations; and complement 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. A Broad Agency Announcement application for the Military Suicide Research Consortium was recommended for funding and will build upon prior work to deliver state-of-the-art, evidence-based, effective suicide prevention tools and interventions to the DoD. Among the identified high-priority areas of TBI that received FY 2015 funds are the Federal Interagency TBI Research Database, advances in neuro-imaging and biomarker detection capabilities, prevention of the progression of TBI, and studies to improve the detection of mild TBI.		
FY 2016 Plans: This Congressional Special Interest initiative is for Traumatic Brain Injury / Psychological Health.		
Congressional Add: 441A - Joint Warfighter Medical Research Program	20.000	20.000
FY 2015 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		

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016
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 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 and full application for the next level of effort. The scientific peer review was in May 2015 and programmatic review occurred in June 2015. Awards will be completed by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Joint Warfighter Medical Research Program.		
Congressional Add: 455A - Therapeutic Service Dog Training Program (USUHS) ***FY 2015 Accomplishments:*** This Congressional Special Interest research initiative is for Therapeutic Service Dog Training Program (USUHS). ***FY 2016 Plans:*** No Funding Programmed. Therapeutic Service Dog Training Program transferred to DHP O&M Account.	3.000	0.000
Congressional Add: 464A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0604110. Funds supported advanced development efforts for medical simulation and information sciences, military operational medicine, and combat casualty care (Project 374A). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0604110. Funds supported advanced development efforts for medical simulation and information sciences, military operational medicine, and combat casualty care (Project 374A).	17.783	30.700
Congressional Adds Subtotals	60.783	72.075

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
434A: *Medical Products Support and Advanced Concept Development (AF)*	6.909	0.000	4.000	4.000	-	4.000	4.000	4.000	4.000	4.080	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 2015	FY 2016	FY 2017
Title: Medical Products Support and Advanced Concept Development (AF)	0.000	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 transition key, high value and impact technologies to operational use. Provide core capability to logically progress initiatives and concepts in the S&T and translational/knowledge-focused programs (6.1-6.3) into material solutions and conduct the advanced development and transition activities needed to ensure those products are fielded in an effective, timely and efficient manner.			
FY 2015 Accomplishments: Awarded effort to refine and commercialize the Cardiovascular Sonospectrographic Analyzer (CSA). Conducted developmental engineering activities to ready the device for inclusion in advanced clinical trials and guiding it to the FDA regulatory approval pathway. Began evaluation of developing a next generation multichannel infusion pump via a modified-commercial approach to rapidly and safely deliver drugs and therapeutics to DoD wounded, ill and injured personnel in the field, in the air and while awaiting evacuation to definitive care.			
FY 2016 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Award effort to begin development of a next generation multi-channel infusion pump via a request for proposal (RFP) approach to provide medics with the ability to rapidly and safely deliver multiple drugs and therapeutics to DoD wounded, ill and injured personnel in the field, in the air and while awaiting evacuation to definitive care. Will also begin transitioning of 59 MDW project for aortic hemostasis and resuscitation balloon treatment for combat casualty care under the Expeditionary Medicine portfolio. We are reaching a point where an Advanced Development investment needs to be made to get a catheter with packaging and inserts for FDA approval and clinical trials. Evaluate the Cardiovascular Sonospectrographic Analyzer (CSA), technology through clinical trials by improving sensitivity and specificity and form factor enhancements to device that can process sound signatures of turbulent blood through partially occluded arteries - target level of sensitivity is CT angiography--include device in ongoing and planned clinical trials for submission of the 510K predicate device application to the FDA. Continue efforts to develop a next generation multi-channel and prepare for predicate device submission to the FDA for transition of the technology. ***FY 2017 Plans:*** Continue development and refinement of the multichannel infusion pump to enable medics in the field to provide multiple drugs and therapeutics simultaneously to DoD wounded, ill and injured personnel in the field, in the air and while awaiting evacuation to definitive care. Will transition 59 MDW project for aortic hemostasis and resuscitation balloon treatment for combat casualty care under the Expeditionary Medicine portfolio in preparation of developing a prototype field catheter with packaging and inserts for eventual FDA approval and pending clinical trials. Evaluation of various technologies to assess operator physiological health and performance, modifiable for field use. Evaluation of candidate technologies to assess airmen environmental hazards. Evaluation of various technologies to assess operator physiological health and performance, modifiable for field use. Evaluation of candidate technologies to assess airmen environmental hazards.			
Accomplishments/Planned Programs Subtotals	0.000	4.000	4.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Partnership with the US Navy, AFRL and the Department of the Interior in inter-agency agreements and use (award of delivery orders and task assignments) to engineering and manufacturing development IDIQ vehicles awarded under SBIR phase III provisions. 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 also utilize the Request for Proposal (RFP) process managed by the Life Cycle Management Center LCMC and awarded by the Air Force Aeronautical Systems Center, Wright-Patterson AFB.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 estabilshed KPPs for same.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	263.991	19.399	19.312	25.340	-	25.340	28.814	24.142	25.370	26.235	Continuing	Continuing
239B: *Health Services Data Warehouse (Air Force)*	1.112	0.654	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
239F: *IM/IT Test Bed (Air Force)*	6.065	1.644	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	0.000	0.908	0.962	-	0.962	1.436	1.461	1.490	1.520	Continuing	Continuing
239H: *IM/IT Test Bed (Air Force) at DHA*	0.000	0.000	1.844	1.837	-	1.837	2.222	2.686	2.740	2.795	Continuing	Continuing
283C: *Medical Operational Data System (MODS) (Army)*	4.856	3.114	2.601	2.678	-	2.678	2.705	2.732	2.759	2.787	Continuing	Continuing
283D: *Army Medicine CIO Management Operations*	3.605	0.000	0.867	0.794	-	0.794	3.491	4.655	4.729	4.977	Continuing	Continuing
283F: *Army Warrior Care and Transition System (AWCTS)*	0.488	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283H: *Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)*	0.000	0.000	0.080	0.080	-	0.080	0.080	0.080	0.000	0.000	Continuing	Continuing
283I: *Workload Management System for Nursing-Internet*	0.264	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283J: *Multi-Drug Resistant Surveillance Network (MRSN)*	1.374	0.738	0.844	0.878	-	0.878	0.000	0.000	0.000	0.000	Continuing	Continuing
283K: *Veterinary Services Systems Management (VSSM)*	0.238	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283L: *Pharmacovigilance Defense Application System*	0.000	0.274	0.275	0.400	-	0.400	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

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency										Date: February 2016		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605013DHA *I Information Technology Development*							
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)*	0.273	0.000	0.362	0.300	-	0.300	0.417	0.331	0.473	0.364	Continuing	Continuing
385A: *Integrated Electronic Health Record Inc 1 (Tri-Service)*	135.319	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
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)*	0.000	1.116	1.346	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
423C: *Defense Center of Excellence (T2T) (DHA)*	0.000	0.000	0.000	1.369	-	1.369	1.395	1.422	1.450	1.479	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)*	0.539	0.348	0.433	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)*	9.848	3.862	1.933	2.326	-	2.326	2.363	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	0.000	6.140	-	6.140	6.025	5.559	6.416	6.901	Continuing	Continuing
480F: *Executive Information/ Decision Support (EI/DS) (Tri-Service)*	5.936	0.000	2.551	1.791	-	1.791	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency										Date: February 2016		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605013DHA *I Information Technology Development*							
480G: *Health Artifact and Image Management Solution (HAIMS) (Tri-Service)*	5.828	2.295	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480K: *integrated Federal Health Registry Framework (Tri-Service)*	2.591	1.061	0.450	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
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)*	4.123	0.016	0.000	1.683	-	1.683	3.500	0.000	0.000	0.000	Continuing	Continuing
480R: *Joint Disability Evaluation System IT (DHA)*	0.000	0.000	0.000	0.445	-	0.445	0.588	0.666	0.679	0.692	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
480Z: *Patient Assessment Screening Tool Outcome Registry (Tri-Service)*	0.000	0.000	0.000	0.828	-	0.828	0.538	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)*	5.526	2.277	2.766	2.829	-	2.829	3.704	4.200	4.284	4.370	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*	1.369	2.000	2.052	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

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); Multidrug-Resistant Organism Repository and Surveillance Network (MRSN); Pharmacovigilance Defense Application System; Corporate Dental System (CDS); Mobile HealthCare Environment (MHCE); and the Defense Center of Excellence (DCoE).

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605013DHA / *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 activities, under the Military Health System, include: Innovation and Advanced Technology; Infrastructure & Operations; Solution Delivery; Information Delivery; Cyber Security; and Portfolio Management and Customer Relations. RDT&E program includes funding for development/integration, modernization, test and evaluation for the Defense Health Agency initiatives, and any special interest that are shared within all components of the Defense Health Program (DHP), excluding the Integrated Electronic Health Record, Defense Medical Information Exchange and the DoD Healthcare Management System Modernization Program (DHMSM).

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

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*

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 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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	21.696	19.312	19.679	-	19.679
Current President's Budget	19.399	19.312	25.340	-	25.340
Total Adjustments	-2.297	0.000	5.661	-	5.661
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	2.000	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-2.888	-			
• SBIR/STTR Transfer	-1.409	-			
• FY 2017 Central IM/IT Investment	-	-	5.661	-	5.661

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605013-Information Technology Development (-$1.409 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$1.409 million).

FY 2016: No change.

FY 2017: Investment to the efense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605013-Information Technology Development (+$5.661 million).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
239B: *Health Services Data Warehouse (Air Force)*	1.112	0.654	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 2015	FY 2016	FY 2017
Title: 239B - Health Services Data Warehouse	0.654	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 2015 Accomplishments: AFMS will continue to use COTS software to 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. Due to funding delays, planned FY15 HSDW accomplishments did not occur in FY15. The funding has been placed on contract, 30 Sep 15, for execution of the planned accomplishment: transition of Clinical Data Mart (CDM) data into the Health Services Data Warehouse (HSDW).			
FY 2016 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.			
FY 2017 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
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	0.654	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	11.267	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
239F: *IM/IT Test Bed (Air Force)*	6.065	1.644	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 2015	FY 2016	FY 2017
Title: 239F IM/IT Test Bed (Air Force)	1.644	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 2015 Accomplishments:

Provided realistic, risk controlled testing to $13B of Central and Service programs. Conducted independent, unbiased assessment of effectiveness, suitability and survivability In Accordance With FAR 46.103, DoD 5000, and AFI 99-103 for the Theater Medical Information Program (TMIP) and Defense Medical Information Exchange (DMIX), both under the Congressional oversight list, and the Enterprise Blood Management System (EBMS). AFMISTB also supported complementary service to existing MHS developmental, integration and interoperability efforts to establish the Defense Health Healthcare Management System Modernization (DHMSM) Operational Medicine (OM) Government Approved Laboratory (GAL) at the AF SG5T Test site at Fort Detrick, MD. Finally, test development and support were provided to half a dozen other ACAT III programs, including the Health Artifact and Imaging Management (HAIMS). Internally, AFMISTB progressed from Initiation to Phase III of the DoD Information

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Assurance Certification and Re-accreditation Process for the AF SG5T Virtual Private Network (VPN) Test Enclave at Port San Antonio, Bldg 1. Also, engaged in seven High Performance Team (HPTs) and Requirements Reviews with AF SG offices. ***FY 2016 Plans:*** 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. 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.			
Accomplishments/Planned Programs Subtotals	1.644	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• N/A: *N/A*	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
239G: *Clinical Enterprise Intelligence Program (CEIP) (DHA)*	0.000	0.000	0.908	0.962	-	0.962	1.436	1.461	1.490	1.520	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 2015	FY 2016	FY 2017
Title: CEIP platform integration	0.000	0.908	0.962
Description: The CEIP platform is a combination of hardware, software and technologists that together deliver the ability to use enterprise clinical data.			
FY 2015 Accomplishments: Previous accomplishment captured under initiative Health Service Data Warehouse Project Code 239B. 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 2016 Plans: 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			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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). 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 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 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).			
Accomplishments/Planned Programs Subtotals	0.000	0.908	0.962

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	0.000	31.778	29.435	-	29.435	29.686	26.888	27.408	27.956	Continuing	Continuing

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
239H: *IM/IT Test Bed (Air Force) at DHA*	0.000	0.000	1.844	1.837	-	1.837	2.222	2.686	2.740	2.795	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 2015	FY 2016	FY 2017
Title: Operational Testing Service	0.000	1.844	1.837
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 2015 Accomplishments:*** Previously reported under initiative IM/IT Test Bed (Air Force) Project Code 239F. ***FY 2016 Plans:*** DHA will transfer the 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. 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. ***FY 2017 Plans:***			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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. Continue ongoing capability development & fielding efforts for half a dozen other ACAT III programs. Initiate Risk Management Framework reaccreditation for AF SG5T VPN for virtualization of IT Test Bed. Participate in at least half a dozen AF SG HPTs and requirement reviews.			
Accomplishments/Planned Programs Subtotals	0.000	1.844	1.837

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
283C: *Medical Operational Data System (MODS) (Army)*	4.856	3.114	2.601	2.678	-	2.678	2.705	2.732	2.759	2.787	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 2015	FY 2016	FY 2017
Title: Medical Operational Data System (MODS)	3.114	2.601	2.678
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 2015 Accomplishments:*** FY 2015 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 MODS Data Warehouse was executed. ***FY 2016 Plans:*** FY 2016 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. ***FY 2017 Plans:*** FY 2017 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 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	3.114	2.601	2.678

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	12.461	12.596	12.984	-	12.984	13.385	13.628	13.878	13.937	Continuing	Continuing
• BA-3, 0807721HP: *Replacement/Modernization*	0.420	0.120	0.620	-	0.620	0.300	0.400	0.200	0.202	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
283D: *Army Medicine CIO Management Operations*	3.605	0.000	0.867	0.794	-	0.794	3.491	4.655	4.729	4.977	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 2015	FY 2016	FY 2017
Title: 283D - Army Medicine CIO Management Operations	0.000	0.867	0.794
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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** For FY 2016, the Army Medicine CIO Management Operations is 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 Army Medicine CIO Management Operations will be developing and enhancing a system that will provide system development, engineering, and testing requirements of Army Medical applications, which will provide realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. These system developments will support the Army's ability to help strengthen the scientific basis for decision-making in patient safety and quality performance within the MHS.			
Accomplishments/Planned Programs Subtotals	0.000	0.867	0.794

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	37.537	39.323	26.312	-	26.312	27.163	27.345	27.320	27.352	Continuing	Continuing
• BA-1, 0807721HP: *Replacement/Modernization*	1.665	0.060	3.186	-	3.186	8.792	9.773	10.339	10.560	Continuing	Continuing
• BA-1, 0807798HP: *Management Headquarters*	3.975	2.463	2.890	-	2.890	2.940	2.992	3.044	3.044	Continuing	Continuing
• BA-1, 0807796HP: *Base Operations*	2.805	0.498	0.510	-	0.510	0.522	0.536	0.536	0.536	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

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: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283F / *Army Warrior Care and Transition System (AWCTS)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
283F: *Army Warrior Care and Transition System (AWCTS)*	0.488	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 Army Warrior Care and Transition System (AWCTS) program includes development projects for Army service level support. Specifically, the AWCTS is a family of systems that allows the integration of multiple business processes under the consolidated oversight of the Warrior Transition Command.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Army Warrior Care and Transition System (AWCTS)	0.000	0.000	0.000
Description: A family of systems that allows the integration of multiple business processes under the consolidated oversight of the Warrior Transition Command. ***FY 2015 Accomplishments:*** No funding programmed. ***FY 2016 Plans:*** No funding programmed. ***FY 2017 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807714HP: *Other Health Activities*	1.691	0.757	0.830	-	0.830	0.416	0.614	0.000	-	Continuing	Continuing
• BA-1, 0807781HP: *Non Central IMIT*	0.816	-	-	-	-	-	-	-	-	Continuing	Continuing

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283F / *Army Warrior Care and Transition System (AWCTS)*

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

1. MEASURE: Increase Soldier's ability to access career and education, and communication with transition coordinators.
METRIC: Days from submitting request to an appointment or obtaining information

2. MEASURE: Provide the capability for staff to be able to gain visibility of a Soldier's transition status.
METRIC: Days from submitting request to receiving status of Soldier.

3. MEASURE: Provide the capability for staff to analyze metrics and business processes.
METRIC: Days from requesting metrics/BP reports until receipt of data.

4. MEASURE: Provide the capability for automated workflow processes to decrease manual and decentralized processes.
METRIC: Percentage of automated processes versus manual processes

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
283H: *Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)*	0.000	0.000	0.080	0.080	-	0.080	0.080	0.080	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 2015	FY 2016	FY 2017
Title: Psychological and Behavioral Health – Tools for Evaluation, Risk, and Management (PBH-TERM)	0.000	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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** FY 2016 funds are being used to add self-service functionality with direct input by the eligible beneficiaries, which improve health system visibility. ***FY 2017 Plans:*** Funding 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	0.000	0.080	0.080

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	0.090	0.000	0.000	-	0.000	0.000	0.000	0.000	-	Continuing	Continuing
• BA-1, 0807714HP: *other health Activities*	0.040	0.060	0.080	-	0.080	0.080	0.080	0.080	0.082	Continuing	Continuing
• BA-1, 0807793DHA: *MHS Tri-Service Information Management/ Information Technology (IM/IT)*	0.000	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.

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

FY16
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.
Source: Audits and analysis performed by Defense Centers of Excellence, Patient-Centered Behavioral Health personnel.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 283I / *Workload Management System for Nursing-Internet*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
283I: *Workload Management System for Nursing-Internet*	0.264	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 Workload Management System for Nursing – Internet (WMSNi) program includes development projects for Army service level support. Specifically, the WMSNi supports clinical staff scheduling, based on known and projected patient care needs, for continuous 24x7 hospital operations.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Workload Management System for Nursing-Internet	0.000	0.000	0.000
Description: 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 Workload Management System for Nursing – Internet (WMSNi) program includes development projects for Army service level support. Specifically, the WMSNi supports clinical staff scheduling, based on known and projected patient care needs, for continuous 24x7 hospital operations. ***FY 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No funding programmed. ***FY 2017 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	0.696	0.298	0.297	-	0.297	0.296	0.297	0.298	-	Continuing	Continuing

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283I / *Workload Management System for Nursing-Internet*

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

1. MEASURE: All Tier 2 tickets were resolved as required.
METRIC: Maintain application including software components resolving 100% of all problems resolvable at the Tier 2 level

2. MEASURE: Hosted Environment up time maintained at 98%.
METRIC: Provide an operational readiness up time of 98% for the hosted environment, excluding scheduled maintenance windows

3. MEASURE: Execute required security patches to enterprise systems IAW Army directives.
METRIC: 95% of Security Patches and critical updates executed within required timeframe

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / *Information Technology Development*	Project (Number/Name) 283J / *Multi-Drug Resistant Surveillance Network (MRSN)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
283J: *Multi-Drug Resistant Surveillance Network (MRSN)*	1.374	0.738	0.844	0.878	-	0.878	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 Multi-Drug Resistant Surveillance Network (MRSN) program includes development projects for Army service level support. Specifically, the MRSN is the Enterprise effort to collect and characterize bacterial isolates to inform best practice, such as patient management and antibiotic selection.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Multi-Drug Resistant Surveillance Network (MRSN)	0.738	0.844	0.878
Description: MRSN is the Enterprise effort to collect and characterize bacterial isolates to inform best practice, such as patient management and antibiotic selection. ***FY 2015 Accomplishments:*** Completed the development and testing of the Phase 2 features of MRSN. Also, started to develop and deploy the First System Update which places the Phase 3 features into production. ***FY 2016 Plans:*** Funding is being used to continue the development and testing of the Phase 3 features of MRSN that were deployed in FY 2015. ***FY 2017 Plans:*** Funding will be used to finalize the development and deployments of the System Updates which places the new Phase 3 features into production. These system developments will support the Army's ability to assist in the rapid, point-of-care diagnostics for decision-making for antibiotic treatment.			
Accomplishments/Planned Programs Subtotals	0.738	0.844	0.878

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	0.565	0.565	0.544	-	0.544	0.757	0.775	0.790	0.790	Continuing	Continuing

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283J / *Multi-Drug Resistant Surveillance Network (MRSN)*

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 MRSN 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: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283K / *Veterinary Services Systems Management (VSSM)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
283K: *Veterinary Services Systems Management (VSSM)*	0.238	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 Veterinary Services Systems Management (VSSM) program includes development projects for Army service level support. Specifically, the VSSM will capture veterinary health care treatment information to include laboratory findings from various medical institutions.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Veterinary Services Systems Management (VSSM)	0.000	0.000	0.000
Description: VSSM is a worldwide web access application capable of capturing veterinary health care treatment information to include laboratory findings of Military working dogs, all government owned animals, and dependent owned animals, and dependent owned animals. ***FY 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	1.208	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	0.000	-	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283K / *Veterinary Services Systems Management (VSSM)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost

Remarks

O&M and Procurement Funding Transferred to DHA starting on OCT2015, per FY16 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

MEASURE: The success of Commercial Laboratories Interface will be the capability in VSSM to electronically request and receive laboratory test results from approved external commercial laboratories, resulting in minable data.

METRIC: The electronic laboratory test result data will be timely, accurate, and allow alerts for potential disease surveillances to be triggered in VSSM.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
283L: *Pharmacovigilance Defense Application System*	0.000	0.274	0.275	0.400	-	0.400	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 2015	FY 2016	FY 2017
Title: Pharmacovigilance Defense Application System (PVDAS)	0.274	0.275	0.400
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 2015 Accomplishments:*** FY 2015 funding allowed the Pharmacovigilance Center to start 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 2016 Plans:*** Funds are being used to finalize the process that provide 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:*** Funding will be used to continue the process that will provide improved information for making military health system formulary decisions. This process improvement will also provide better visibility into medical practice enhancing patient safety, and greater access to drug risk/benefit information for military physicians.			
Accomplishments/Planned Programs Subtotals	0.274	0.275	0.400

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	1.118	1.205	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
• BA-1, 0807714HP: *Other Health Activities*	0.035	0.000	0.980	-	0.980	0.996	1.053	2.061	2.011	Continuing	Continuing
• BA-1, 0807798HP: *Management Headquarters*	1.395	1.418	1.500	-	1.500	1.550	1.600	1.650	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

1. MEASURE: All Tier 2 tickets were resolved as required.
METRIC: Maintain application including software components resolving 100% of all problems resolvable at the Tier 2 level

2. MEASURE: Hosted Environment up time maintained at 98%.
METRIC: Provide an operational readiness up time of 98% for the hosted environment, where the application is never inoperable for longer than 3 business days

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Business Intelligence Competency Center (BICC)	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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	1.565	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	0.000	-	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Corporate Dental System (CDS)	0.000	0.000	0.000
Description: The Corporate Dental System (CDS) is the Dental digital web based DICOM image capture and viewing application. ***FY 2015 Accomplishments:*** FY 2015 funds were used to finalize required imaging capabilities at USA dental facilities to include DICOM image view, capture, store, and forward. Corporate Dental Imaging (CDI) 1.0 provides the capability to scan the patient's CAC which also verifies patient metadata within DEERS. CDI 1.0 can now capture images using the hardware vendor's Software Development Kit (SDK) for image enhancement and filtering rather than a TWAIN driver. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Managment/ Information Technology*	2.464	1.438	0.111	-	0.111	0.112	0.114	0.115	0.117	Continuing	Continuing
• BA-1, 0807715HP: *Dental Care Activities*	8.260	8.758	12.772	-	12.772	13.051	13.386	13.656	13.851	Continuing	Continuing
• BA-3, 0807721HP: *Replacement/Modernization*	2.100	2.541	0.600	-	0.600	0.600	0.600	0.600	0.600	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 283N / *Corporate Dental System (CDS)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
283P: *Mobile HealthCare Environment (MHCE)*	0.273	0.000	0.362	0.300	-	0.300	0.417	0.331	0.473	0.364	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 2015	FY 2016	FY 2017
Title: Mobile HealthCare Environment (MHCE)	0.000	0.362	0.300
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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** FY 2016 certification/funding will be 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 will be utilized to continue the expanding of the MHCE functionality deployed in FY 2016, 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 MHS.			
Accomplishments/Planned Programs Subtotals	0.000	0.362	0.300

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	1.226	1.285	1.350	-	1.350	1.416	1.489	1.564	1.640	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
385A: *Integrated Electronic Health Record Inc 1 (Tri-Service)*	135.319	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 2015	FY 2016	FY 2017
Title: Integrated Electronic Health Record (iEHR) Inc 1 (Tri-Service)	0.000	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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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	0.000	0.00	0.00

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. Program cost, schedule and performance are measured periodically using a systematic approach.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)	0.000	0.000	0.000
Description: Work with Department of Veterans Affairs (VA), Department of Health & Human Services (HHS), and Private Sector to expand VLER. ***FY 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807793HP: *MHS Tri-Service Information*	-	-	-	-	-	-	-	-	-		

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Defense Center Of Excellence (FHP&RP)	0.000	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 2015 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 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

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
423B: *Defense Center of Excellence (Army)*	0.000	1.116	1.346	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 United States 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 2015	FY 2016	FY 2017
Title: Defense Center of Excellence (Army)	1.116	1.346	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 2015 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
FY 2015 funds were used to continue the development, modernization, sustainment, and release of mobile apps, PH games, websites, and longitudinal services in support of the T2 Toolkit portfolio. This new generation of PH mobile apps, games, and websites are improving the PH outcomes for DoD Service Members, their Families, and Veterans. Continued for 2016 is the use of RDT&E funds for the Deployment Health Clinical Center's (DHCC) development of a module (FIRST STEPS) in support of Psychological and Behavioral Health. This expansion effort is intended to further the focus of the behavioral healthcare of all adult primary care. ***FY 2016 Plans:*** FY 2016 funds are being used to complete the development and transition to sustainment for the electronic capabilities listed above. The T2 toolkit and its sub-components will be more fully developed in order to allow for further collaboration and remote access to tools. RDT&E funding will be utilized to continue development of mobile applications, 3D games, websites, and other applications. In addition, the DHCC FIRST STEPS module will continue 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 will also add healthcare facilitators in behavioral activation and motivational interviewing techniques with patients. ***FY 2017 Plans:*** Management of funds is transferred from Army to DHA effective in FY 2017.			
Accomplishments/Planned Programs Subtotals	1.116	1.346	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	1.786	-	-	-	-	-	-	-	-	Continuing	Continuing
• BA-1, 0807724HP: *Military Unique - Other Medical*	0.268	-	-	-	-	-	-	-	-	Continuing	Continuing

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.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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) (DHA)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
423C: *Defense Center of Excellence (T2T) (DHA)*	0.000	0.000	0.000	1.369	-	1.369	1.395	1.422	1.450	1.479	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury is administratively managed under the United States Army Medical Command (MEDCOM) Organization that provides guidance across DoD program related to psychological health (PH) and traumatic brain injury (TBI) issues. The organizational mission statement is: "DCoE's mission is to improve the lives of our nation's Service Members, Families, and Veterans by advancing excellence in psychological health and traumatic brain injury prevention and care." 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 2015	FY 2016	FY 2017
Title: Defense Center of Excellence (DHA)	0.000	0.000	1.369
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 2015 Accomplishments: No Funding Programmed.			
FY 2016 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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) (DHA)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
No Funding Programmed. ***FY 2017 Plans:*** Management of funds is transferred from Army to DHA in beginning in FY17. FY17 funds will be used to complete the development, and to transition to sustainment for the electronic capabilities deployed in FY16. The Telehealth and Technology Toolkit (T2T) and its sub-components will be more fully developed in order to allow for further collaboration and remote access to tools. RDT&E funding will be utilized to continue development of mobile applications, 3D games, websites, and other applications.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	1.369

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information Management/ Information Technology (IM/IT)*	0.000	0.000	2.159	-	2.159	2.198	2.239	2.284	2.330	Continuing	Continuing
• BA-1, 0807724DHA: *Military Unique Requirements - Other Medical - Health Care*	0.000	0.000	3.733	-	3.733	3.768	3.808	3.863	3.940	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. Program cost, schedule and performance are measured periodically using a systematic approach.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**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: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Title: NICOE Continuity Management Tool	0.000	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 2015 Accomplishments:*** No funding programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• 4187 807783: *NCMT*	0.000	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing
• 4187 807781: *NCMT*	3.961	4.107	4.259	-	4.259	4.332	-	-	-	Continuing	Continuing
• 1690 807781: *HEIS*	0.000	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing
• 4859 807781: *JMED*	0.000	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing
• 4940 807781: *JTFCMI*	40.792	41.610	42.395	-	42.395	43.267	-	-	-	Continuing	Continuing
• 4940 807720: *JTFCMI*	4.600	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing
• 4273 807781: *Engineering and Deployment*	0.000	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• 4280 807721: *Engineering and Deployment*	0.000	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing
• 4361 807781: *IA Operational Resiliency*	0.000	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing
• 4126 807781: *Computer Network Defense*	0.000	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing
• 4111 807781: *Computer Network Defense*	0.473	0.482	0.492	-	0.492	0.502	-	-	-	Continuing	Continuing
• 4165 807781: *Computer Network Defense*	0.000	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing
• 4177 807781: *Computer Network Defense*	0.000	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing
• 4364 807781: *Workforce Development*	0.000	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: PB 2017 Defense Health Agency		Date: February 2016
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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
446A: *Disability Mediation Service (DMS)*	0.539	0.348	0.433	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 2015	FY 2016	FY 2017
Title: Disability Mediation Service (DMS)	0.348	0.433	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.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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." ***FY 2015 Accomplishments:*** Funding transferred to Joint Disability Evaluation System IT Project Code 480R since responsibility has moved to new program office starting in FY 2017. ***FY 2016 Plans:*** Funding transferred to Joint Disability Evaluation System IT Project Code 480R since responsibility has moved to new program office starting in FY 2017. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.348	0.433	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Defense Medical Human Resources System (internet) (DMHRSi) (Tri-Service)	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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
480C: *Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)*	9.848	3.862	1.933	2.326	-	2.326	2.363	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

DMLSS provides the Military Medical Departments one standard Department of Defense (DoD) medical logistics system. The DMLSS suite of applications provides the healthcare driven capability to support the medical logistics needs of the DoD community for critical medical commodities - pharmaceuticals and medical/surgical supplies across the 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) Defense Supply Center Philadelphia and the Military Health System (MHS) providing an industry to practitioner supply chain for the medical commodity. The DMLSS Defense Logistics Agency Wholesale (DMLSS-W) applications are funded by Defense Logistics Agency while the garrison medical treatment facilities and theater applications are funded by the Defense Health Program. The current DMLSS system provides full spectrum capability for medical logistics management. Basic functionality includes 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 medical treatment facility physical plant and supports Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) accreditation requirements. DMLSS, in coordination with the Theater Medical Information Program – Joint (TMIP-J), is providing to the Services and the Combatant Commanders the functional logistics capabilities necessary to rapidly project and sustain joint medical capabilities for medical logistics management of theater medical materiel operations. Current 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 the lower levels of care, and allows non-logisticians, who maintain their medical supplies as an additional duty, to electronically exchange catalog, order, and status information with their supply activity.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)	3.862	1.933	2.326
Description: Development, integration and modernization of DMLSS modules.			
FY 2015 Accomplishments: Made the following critical functional and technical changes in the Medical Logistics: (1) Implemented additional pharmaceutical ordering logic and catalog data; (2) Implemented additional business logic to support equipment maintenance planning and equipment lifecycle management; (3) Expanded the Master Ordering Facility functionality to support Department of Defense support of Civil Authorities contingency operations; (4) Provided foundational support for regionalization of DMLSS application, reducing the deployed footprint without compromise in performance and quality.			
FY 2016 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Objectives are (1) to continue to support DMLSS Regionalization and data consolidation, reducing the deployed footprint (Hardware (HW) and License), without compromise in performance and quality, and increasing access to near real time information; (2) create standard messaging for Medical Material Quality Control (MMQC) recalls and hazard alerts: (3) and establish foundational data objects, definitions and schema to support industry base changes required by The Drug Supply Chain Security Act. ***FY 2017 Plans:*** Objectives are to continue to support Medical Material Quality Control (MMQC) recalls and hazard alerts standard messaging and authoritative data sources as well as to continue to acquire foundational data objects, definitions and schema to support industry base changes required by The Drug Supply Chain Security Act.			
Accomplishments/Planned Programs Subtotals	3.862	1.933	2.326

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	35.755	30.889	32.511	-	32.511	33.075	33.639	34.313	34.999	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
480D: *Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)*	8.052	0.000	0.000	6.140	-	6.140	6.025	5.559	6.416	6.901	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 2015	FY 2016	FY 2017
Title: Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)	0.000	0.000	6.140
Description: Configure, enhance and interface DOEHRS-IH modules. ***FY 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** Funding for the Critical User Enhancements Phase III will resolve the high-priority System Change Requests to address the Occupational Environmental Health Integrated Product Team (OEHIPT)-identified Critical User Enhancements, the end users will remain unable to fully utilize DOEHRS-IH effectively to efficiently meet the mission of longitudinal exposure recordkeeping and reporting across the range of military operations (ROMO). OEH surveillance data collected in garrison, during deployment health operations, and in association with public health emergency management supports joint OEH data management, informs OEH risk assessment and management, and results in actionable data and reports to commanders to ensure emission success,			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
preserve readiness and sustain the force. Critical User Enhancements Phase III will focus on the following areas of the application: Managing and Validating of Exposure Data, Personnel Management and Assignments, Record Search Capabilities, User Role Management and Control of Functionality by Role, Workflow and End User Experience, and resolving technical SCRs in these critical areas which are key to increasing user satisfaction with the application and, thereby, increasing usage of the DOEHRS-IH system and the value of the OEH surveillance data.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	6.140

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	6.600	9.579	12.262	-	12.262	14.835	14.886	15.864	17.030	Continuing	Continuing
• BA-3, 0807721DHA: *Replacement/Modernization*	0.239	0.113	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
480F: *Executive Information/ Decision Support (EI/DS) (Tri-Service)*	5.936	0.000	2.551	1.791	-	1.791	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

EI/DS is 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Executive Inforamtion/Decision Support (EI/DS) (Tri-Service)	0.000	2.551	1.791
Description: Development, modernization, upgrades and testing for various EI/DS modules. ***FY 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** ESSENCE • Develop the Enhanced Query capabilities which will substantially expand the scope of the current query functionality • Develop an Enhanced Reference table management capability to update key reference tables within ESSENCE • Develop an Enhanced System Administration to maintain mapping tables, site Identification, case-specific definitions, site definitions, etc. TED • Provide capability to download National Plan and Provider Enumeration System (NPPES) file and to match National Provider Identifier (NPI) and Provider Record within TED PEPR			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
• Modify PEPR to report revenue codes and NPI EI/DS will continue to: (1) improve users' capabilities to review current and future data sources; (2) improve business decisions and reporting efforts; (3) improve sharing capabilities among internal and external organizations; (4) sustain and maintain applications to continue and improve business processes; (5) support healthcare management and information delivery to support managers, clinicians, and analysts. ***FY 2017 Plans:*** ESSENCE • Expand data storage/maintenance/access to 5 years from 18 months for near-real-time health surveillance. • Implement geographic information system (GIS) capability within ESSENCE to display spatial detection results and point source of counts by patient's residence through heat maps. • Provide analysis of encounter-related laboratory positive results data to design specific case definitions and allows users to determine the proportion of Influenza-Like Illness (ILI) cases due to a specific pathogen. • Design (preliminary only) access and ingest denominator data to calculate rates for each syndrome or category.			
Accomplishments/Planned Programs Subtotals	0.000	2.551	1.791

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	26.280	31.070	32.080	-	32.080	32.586	33.298	33.964	34.645	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
480G: *Health Artifact and Image Management Solution (HAIMS) (Tri-Service)*	5.828	2.295	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 2015	FY 2016	FY 2017
Title: Health Artifact and Image Management Solution (HAIMS) (Tri-Service)	2.295	0.000	0.000
Description: Integrate new functionality into HAIMS. ***FY 2015 Accomplishments:*** Supported operational test and evaluation activities for FY14 modernization efforts. $2M O&M of the FY15 $3.6M O&M congressional add were reprogrammed to $2M RDT&E. This additional $2M RDT&E funds will extend the Service Treatment Record (STR) Tracker Proof of Concept pilot efforts to FY16 to cover: a) continued COTS configuration using Agile principles, b) integration, c) ongoing testing and evaluation activities, d) documentation, e) completion of the Information Assurance certification and accreditation process to support an Authority To Operate (ATO), and f) development of the solution into production with a limited number of users for 6 months to a year to obtain user feedback. The funds will also support the evaluation of the STR Proof of Concept against exit criteria ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	2.295	0.000	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	17.054	17.575	25.634	-	25.634	25.298	22.398	22.919	23.377	Continuing	Continuing
• BA-3, 0807721DHA: *Replacement/Modernization*	1.991	9.500	12.500	-	12.500	12.604	13.732	14.007	14.287	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
480K: *integrated Federal Health Registry Framework (Tri-Service)*	2.591	1.061	0.450	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 2015	FY 2016	FY 2017
Title: integrated Health Registry Framework (Tri-Service)	1.061	0.450	0.000
Description: Develop, integrate and test a common registry. ***FY 2015 Accomplishments:*** Funding to support a consolidated technical approach for the Centers of Excellence, which will provide a repeatable process that includes integration of their registry requirements into federated subspecialty clinical data elements that were determined by representative subject matter experts from the Tri-Services and Veteran's Affairs. ***FY 2016 Plans:*** Additional funding added in FY 2016 to finalize all development and testing necessary for a consolidated technical approach. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	1.061	0.450	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	3.207	2.838	2.865	-	2.865	2.913	2.962	3.018	3.079	Continuing	Continuing
• BA-3, 0807721DHA: *Replacement/Modernization*	0.000	0.015	0.094	-	0.094	0.066	0.040	0.041	0.042	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Theather Medical Information Program - Joint (TMIP-J) (Tri-Service)	0.000	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 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			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 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

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
480P: *Other Related Technical Activities (Tri-Service)*	4.123	0.016	0.000	1.683	-	1.683	3.500	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 2015	FY 2016	FY 2017
Title: Other Related Technical Activities (Tri-Service)	0.016	0.000	1.683
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 2015 Accomplishments:*** Activities common to multiple or all Tri-Service systems/programs and cannot be associated with any one individual Tri-Service initiative such as interest penalty. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** Funding in support of Health Information Technology Shared Services investment.			
Accomplishments/Planned Programs Subtotals	0.016	0.000	1.683

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-3, 0807721DHA: *Replacement/Modernization*	0.000	0.000	2.310	-	2.310	2.730	0.000	0.000	0.000	Continuing	Continuing

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
480R: *Joint Disability Evaluation System IT (DHA)*	0.000	0.000	0.000	0.445	-	0.445	0.588	0.666	0.679	0.692	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 2015	FY 2016	FY 2017
Title: Joint Disability Evaluation System IT (JDES-IT)	0.000	0.000	0.445
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 2015 Accomplishments:*** Funding will be used for JDES-IT requirements when a approach has been determined and finalized. ***FY 2016 Plans:*** Funding will be used for JDES-IT requirements when a approach has been determined and finalized. ***FY 2017 Plans:*** Funding will be used for JDES-IT requirements when a approach has been determined and finalized.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.445

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

To be determined when an approach has been finalized.

E. Performance Metrics

To be determined when an approach has been finalized.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Clinical Case Management (Tri-Service)	0.000	0.000	0.000
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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 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

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
480Z: *Patient Assessment Screening Tool Outcome Registry (Tri-Service)*	0.000	0.000	0.000	0.828	-	0.828	0.538	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 2015	FY 2016	FY 2017
Title: Patient Assessment Screening Tool Outcome Registry (PASTOR) (Tri-Service)	0.000	0.000	0.828
Description: PASTOR is a GOTS based clinical information system that provides standardized pain assessment with an outcome registry to promote consistency in pain care delivery. 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). • Capability to identify and enroll patients in a pain management registry (which is a part of the PASTOR package and maintained at Madigan).			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
FY 2015 Accomplishments: No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** Development/integration to: 1) Provide pain patient focused outcomes data to improve clinical decision making 2) Develop data driven and military specific clinical practice guidelines 3) Obtain critical data to assure needs based alignment of resources and 4) Integrate existing validated outcome measures into PASTOR (data is collected and is waiting on analysis)			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.828

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	0.000	0.000	1.138	-	1.138	1.221	0.000	0.000	0.000	Continuing	Continuing
• BA-3, 0807721DHA: *Other Procurement, Replacement/Modernization*	0.000	0.000	0.864	-	0.864	0.065	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Theather Enterprise Wide Logistics System (TEWLS) Tri-Service)	0.000	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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
482A: *E-Commerce (DHA)*	5.526	2.277	2.766	2.829	-	2.829	3.704	4.200	4.284	4.370	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 2015	FY 2016	FY 2017
Title: E-Commerce (DHA)	2.277	2.766	2.829
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-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			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 2015 Accomplishments:*** - Continue compliance enhancements and modernization of financial processing and reporting. Enhance application functionality to respond to changes in health care policy and guidance, to improve operational efficiency, and to continue providing operational personnel with effective financial, contract management, and acquisition support capabilities. Enhance health care claims and financial processing to accommodate changes in health care requirements and to improve contractor performance assessment and deliverable processing. Implement accounting improvements to support user interface processing, audit support, financial and audit reporting, and enterprise budget management. Finally, implement software changes, mandated by Congress and the DoD, to accommodate financial application health care policy modifications, and BEA SFIS changes. ***FY 2016 Plans:*** Continue compliance enhancements and modernization of healthcare financial processing, contract operations, and financial reporting. Enhance 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. Enhance 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. Enhance accounting and finance capabilities to improve the tracking of pharmaceutical manufacturer refunds, dispute handling, collections, and case management. Implement accounting improvements to support healthcare accounting operations, financial audit support, financial reporting, and private sector care budget management. Finally, implement software changes, mandated by Congress and the DoD, to accommodate financial application healthcare policy modifications, BEA SFIS changes, and PDS compliance. ***FY 2017 Plans:*** Continue compliance enhancements and modernization of healthcare financial processing, contract operations, and financial reporting. Enhance 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. Enhance 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. Enhance accounting and finance capabilities to improve the tracking of pharmaceutical manufacturer refunds, dispute handling, collections, and case management. Implement accounting improvements to support healthcare accounting operations, financial audit support, financial reporting, and private sector care budget management. Finally, implement			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
software changes, mandated by Congress and the DoD, to accommodate financial application healthcare policy modifications, BEA SFIS changes, and PDS compliance.			
Accomplishments/Planned Programs Subtotals	2.277	2.766	2.829

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807752HP: *Miscellaneous Support Activities*	14.443	14.615	14.933	-	14.933	14.438	14.286	14.543	-	Continuing	Continuing
• BA-3, 0807721HP: *Replacement/Modernization*	0.000	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Navy Medicine Chief Information Officer (CIO) Management Operations	0.000	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 2015 Accomplishments: No Funding Programmed.			
FY 2016 Plans: No Funding Programmed.			
FY 2017 Plans: No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807781HP: *Non-Central Information Management/ Information Technology*	160.215	82.274	82.427	-	82.427	83.778	68.129	71.102	72.458	Continuing	Continuing
• BA-1, PE 0807795HP: *Base Communications - CONUS*	16.796	16.835	17.153	-	17.153	17.458	17.793	18.151	18.505	Continuing	Continuing
• BA-1, PE 0807995HP: *Base Communications - OCONUS*	2.458	2.505	2.552	-	2.552	2.599	2.646	2.696	2.750	Continuing	Continuing
• BA-3, PE 0807721HP: *Replacement/Modernization*	1.107	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
490J: *Navy Medicine Online*	1.369	2.000	2.052	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

NMO provides for management of Navy medical/dental data in a data warehouse to support Navy operational commanders and Navy Medicine/Dental personnel in managing and reporting individual medical/dental readiness. This data is received from all Navy ships/submarines from source applications/ modules/systems such as Theater Medical Information Program-Maritime (TMIP-M), Maritime Medical Modules (MMM), and Dental Common Access System (DENCAS). The data is then provided to other systems/applications/modules such as Medical Readiness Reporting System (MRRS) to support medical readiness reporting, including individual readiness. NMO also provides logistic reporting for Navy operational units that allows analysis of the Navy's Authorized Minimum Medical Allowance List/Authorized Dental Allowance List (AMMAL/ADAL) data. In addition, NMO provides case management tools that provide an automated means to input and track waiver requests through their approval or disapproval. The tools are used to support medical waiver requests for USN/USMC officer accessions programs, medical waiver requests for USMC enlistments, medical waiver requests for basic training medical issues for USN/USMC, incapacitation of dependent waiver requests, special duty medical waivers requests for submarines, spec ops, etc., and it also tracks medical issues that may impact USNA midshipmen service selection and commissioning.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Navy Medicine Online (NMO)	2.000	2.052	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 2015 Accomplishments:*** This is an ongoing activity recently enacted by the Navy Medicine IM/IT process which further defines/transforms future IM/IT Medical Program Enhancements and Medical Capabilities. ***FY 2016 Plans:*** Funding transferred from Navy Medical Information Technology to Defense Health Agency Health Information Technololgy in FY 2016. RDT&E funds for mobility will be used for application platform usability and interoperability to deliver apps for patients and staff. Will continue research on secure communications, as well hosting and accessing data at rest. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	2.000	2.052	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605013DHA / *Information Technology Development*	**Project (Number/Name)** 490J / *Navy Medicine Online*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	19.912	28.514	0.248	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)*	12.634	28.514	0.248	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

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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	68.267	9.216	8.125	-	8.125
Current President's Budget	28.514	0.248	0.000	-	0.000
Total Adjustments	-39.753	-8.968	-8.125	-	-8.125
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-8.968			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-26.699	-			
• SBIR/STTR Transfer	-13.054	-			
• FY 2017 Component Directed Realignment of Funding to DHMSM	-	-	-8.125	-	-8.125

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605023-Integrated Electronic Health Record (iEHR) (-$13.054 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$13.054 million).

FY 2015: Net of reprogramming actions to the Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605023-Integrated Electronic Health Record (iEHR) (-$26.699 million).

FY 2016: Congressional Directed Reduction to the Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605023-Integrated Electronic Health Record (iEHR) (-$8.968 million).

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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)*

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605023-Integrated Electronic Health Record (iEHR) (-$8.125 million) to DHP RDT&E PE 0605026- DoD Healthcare Management System Modernization (DHMSM) (+$8.125 million).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
444A: *Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)*	12.634	28.514	0.248	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 2015	FY 2016	FY 2017
Title: Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX) (Tri-Service)	28.514	0.248	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: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 2015 Accomplishments:*** • DMIX has successfully deployed 2 major releases, 1 software patch, conducted an operational assessment, as well as a “blue team” penetration testing assessment, and delivered five Builds of DoD data maps. The three releases in FY2015 included: Viewer Patch (December 2014), Release 2 (March 2015), and Release 3 (September 2015): o The Viewer Patch blocked DoD users from viewing VA immunization data and added a banner to reflect VA data is not complete and added VA Immunization Terminology Maps. DoD functional community provided this as a requirement and wanted this feature added for DoD as the VA allows patients to "self-report" immunizations. DoD does not allow or recognize self-reported immunizations. o Release 2 provided end users with the ability to view the remaining data domains with defined standards, blocked users from viewing “blacklisted” patient medical information (patient information that is highly sensitive such as the President or a member of Congress), and integrated Joint Legacy Viewer (JLV) into the AHLTA client menu enabling AHLTA users to access JLV from AHLTA. A future release will incorporate a FCLG approved update to change “JLV” to “Health Information Portal” (HIP) within the AHLTA menu. These accomplishments will support the enterprise wide deployment of JLV. o Release 3 collapsed enterprise viewers (VLER, Bidirectional Health Information Exchange (BHIE)-AHLTA, and BHIE-SHARE) into the single viewer capability, defined the delta between existing functionality and JLV functionality, and added available private sector data for DoD patients into each applicable widget as well as a single community healthcare widget. Release 3 collapsed the VLER and BDA adaptors into the DMIX Data Exchange Services. • Specifically the major releases also added the additional functionality: o Single Sign on- Context Management for AHLTA users to include a link to JLV inside of the AHLTA tree o Patient search by electronic data interchange personal identifier (EDIPI)			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
o Added 4 new clinical data domains to display standardized terms o Collapsed multiple viewer key functionality and capabilities into the single JLV viewer o Complied with ICD-10 mandate o Enhanced patient search to allow a patient to be selected from a list of recently viewed patients o Enhanced “break the glass” capability in order to allow the viewing of sensitive DoD records o DMIX Viewer Component Milestone C achieved Sept 2015 ***FY 2016 Plans:*** Small Business Innovation Research ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	28.514	0.248	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, PE 0807784DHA: *Information Technology Development* -	61.901	18.300	17.183	-	17.183	16.284	16.505	17.958	16.883	Continuing	Continuing
• BA-3, 0807784DHA: *Replacement/Modernization*	3.199	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: DoD Healthcare Management System Modernization (DHMSM)	0.000	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 2015 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
No Funding Programmed.. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 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

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Virtual Lifetime Electronic Record (VLER) HEALTH	0.000	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 2015 Accomplishments: No Funding Programmed.			
FY 2016 Plans: No Funding Programmed.			
FY 2017 Plans: No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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	0.000	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-3, PE 0807784: *Replacement/ Modernization, Integrated Electronic Health Record*	0.000	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.

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605025DHA / *Theater Medical Information Program - Joint (TMIP-J)*							
COST ($ in Millions)	**Prior Years**	**FY 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	23.783	21.403	22.100	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)*	23.783	21.403	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
445B: *Operational Medicine Support*	0.000	0.000	22.100	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

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.

Operational Medicine Support (OpMedSpt):Due to the unique nature of the operational environment, the Military Health System must modernize the following capabilities: medical command and control (MC2); medical situational awareness (MSA) (aggregation of operational medical data at a classified level, denying the enemy access to data which could reveal operational plans); Defense blood management; assemblage management; and data interoperability with the pending EHR solution and operational allies. The clinical needs of the operational community are to be met by the pending EHR solution, but there are functional needs, outside the capture of clinical data, to inform decision making regarding the ability of the MHS to meet the needs of the medically ready force, to support the joint warfighter and share data with line systems. It will support mission delivery and execution through the maximization of information technologies, driving standards compliance to ensure non-EHR capabilities will effectively consume the data created through the use of the pending EHR solution in the operational environment, and to allow the solution to share data with these other capabilities, eliminating the need for one to one interfaces, their limitations and cost. Along with the need to modernize those non-clinical capabilities, this enterprise's risk mitigation strategy also supports ongoing missions and clinical needs in the operational environment until sufficient testing of pending solutions can be accomplished in environments indicative of the operational environments, tactical, mobile and dismounted. TMIP-J (MSAT, TMDS, DCAM, TRAC2ES,

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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)*

AHLTA-T, MCC (formerly AHLTA-Mobile), Single Sign On, MMM, SAMS, and TC2) is the "umbrella" system for these solutions and the functional capabilities they support and achieves Full Operational Capability (FOC) in FY15. While the modernization of the operational environment clinical solutions (AHLTA-T, MCC (AHLTA-Mobile) and TC2) is planned to take place under the auspices of the pending EHR solution, there is currently no such plan for the non-EHR capability modernization activities. The Operational Medicine project was created to ensure the MHS is able to meet the needs of the joint warfighter, line and higher level headquarters for MC2, MSA, Defense blood management and assemblage management.

B. Program Change Summary ($ in Millions)	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	22.042	22.100	22.140	-	22.140
Current President's Budget	21.403	22.100	0.000	-	0.000
Total Adjustments	-0.639	0.000	-22.140	-	-22.140
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.639	-			
• Realignment to new DHP RDT&E PE 0605045-Joint Operational Medicine Information System (JOMIS)	-	-	-22.140	-	-22.140

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605025-Theater Medical Information Program – Joint (TMIP-J) (-$0.639 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$0.639 million).

FY 2016: No change.

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605025-Theater Medical Information Program - Joint (TMIP-J) (-$22.140 million) to DHP RDT&E PE 0605045-Joint Operational Medicine Information System (JOMIS) (+$22.140 million).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
445A: *Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)*	23.783	21.403	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

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 2015	FY 2016	FY 2017
Title: Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)	21.403	0.000	0.000
Description: Complete Increment 2 Release 2 (I2 R2) and Increment 2 Release 3 (I2 R3) development/integration and conduct operational testing/operational assessment.			
FY 2015 Accomplishments: Completed system integration and testing for Increment 2 Release 3 (I2R3) and held a successful I2R3 Test Readiness Review in First Quarter of FY 2015.			
FY 2016 Plans: No Funding Programmed.			
FY 2017 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	21.403	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807793DHA: *MHS Tri-Service Information*	53.604	62.170	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	0.000	49.857	-	49.857	37.504	32.624	27.698	22.552	Continuing	Continuing
• BA-3, 0807744DHA: *Theater Medical Information Program - Joint (TMIP-J)*	3.145	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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
445B: *Operational Medicine Support*	0.000	0.000	22.100	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

This initiative supports executive directives and legal mandates to ensure "…every Soldier, Sailor, Airman and Marine will have a comprehensive, life-long medical record…"(Source: Special report of the Presidential Advisory Committee on Gulf War Veterans' Illness, 1997) and "The Secretary of Defense shall establish a system to assess the medical condition of members of the Armed Forces…who are deployed" (Source: Title 10; Section 1074f (1997): Medical tracking system for members deployed overseas). It also supports the June 21, 2013 acquisition decision memorandum from the Undersecretary of Defense for Acquisition, Technology and Logistics to "…focus on the goal of acquiring a replacement for the DoD legacy Military Health System (MHS) clinical systems including but not limited to…the EHR component of the Theater Medical Information Program with the objective of fielding a modernized replacement by 2017."

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Operational Medicine Support	0.000	22.100	0.000

Description: It will support mission delivery and execution through the maximization of information technologies, driving standards compliance to ensure non-EHR capabilities will effectively consume the data created through the use of the pending EHR solution in the operational environment, and to allow the solution to share data with these other capabilities, eliminating the need for one to one interfaces, their limitations and cost.
Along with the need to modernize those non-clinical capabilities, this enterprise's risk mitigation strategy also supports ongoing missions and clinical needs in the operational environment until sufficient testing of pending solutions can be accomplished in environments indicative of the operational environments, tactical, mobile and dismounted. TMIP-J (MSAT, TMDS, DCAM, TRAC2ES, AHLTA-T, MCC (formerly AHLTA-Mobile), Single Sign On, MMM, SAMS, and TC2) is the "umbrella" system for these solutions and the functional capabilities they support and achieves Full Operational Capability (FOC) in FY15. While the modernization of the operational environment clinical solutions (AHLTA-T, MCC (AHLTA-Mobile) and TC2) is planned to take place under the auspices of the pending EHR solution, there is currently no such plan for the non-EHR capability modernization activities. The Operational Medicine project was created to ensure the MHS is able to meet the needs of the joint warfighter, line and higher level headquarters for MC2, MSA, Defense blood management and assemblage management.

FY 2015 Accomplishments:
Not applicable. This initiative was previously reported under TMIP-J funding profile but is being pulled out separately for the FY 2016 budget submission for transparency. Funding Joint Operational Medicine Information System (JOMIS) begins in FY 2016.

FY 2016 Plans:
Funding will be used for Joint Operational Medicine Information System (JOMIS).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
• Continue to support the DMLSS Regionalization and data consolidation, reducing the deployed footprint (Hardware and Software), without compromise in performance and quality. • EHR Product Evaluation will be conducted by the JOMIS Program Management Office (PMO) in collaboration with the DHMSM Program and will include the following activities: - Identify of existing operational medicine requirements from approved sources, - Organize operational medicine requirements utilizing Capability Development Document (CDD) Capability Taxonomy, - Evaluate the modernized EHR product capability against known, legacy operational medicine requirements, - Review and validate results with MHS Functional Champion and designated representatives, - Generate and validate new, non-EHR related operational medicine requirements in Joint Requirements Oversight Council (JROC)-approved CDD, assembled by DHA (Healthcare Operations), - Evaluate broader non-EHR requirements captured in CDD. • Joint Requirements Oversight Council approved CDD for evolving operational medicine requirements to be addressed in JOMIS future releases (post-IOC). • Test & Evaluation (T&E) Fielding Authorization-to-Proceed (ATP) for Release I (thru Initial Operating Capability (IOC)). • Request for Proposals ATP for JOMIS Releases as part of IOC. JOMIS will be reported under PE 0605045DHA in FY17 and out per Departmental direction for increased transparency. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	22.100	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-3, 0807744DHA: *Theater Medical Information Program - Joint*	0.000	1.494	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.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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*

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: PB 2017 Defense Health Agency	Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
Total Program Element	0.000	88.744	438.376	298.623	-	298.623	42.549	10.326	10.071	10.743	Continuing	Continuing
483A: *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA*	0.000	88.744	438.376	298.623	-	298.623	42.549	10.326	10.071	10.743	Continuing	Continuing

Program MDAP/MAIS Code:
Project MDAP/MAIS Code(s): 496

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.

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.

B. Program Change Summary ($ in Millions)	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	91.394	438.376	260.501	-	260.501
Current President's Budget	88.744	438.376	298.623	-	298.623
Total Adjustments	-2.650	0.000	38.122	-	38.122
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-2.650	-			
• FY 2017 Investment to DoD Healthcare Management System Modernization	-	-	38.122	-	38.122

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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 2015: Realignment 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) (-$2.650 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$2.650 million).

FY 2016: No Change

FY 2017: Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605026-Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) Investment (+$38.122 million).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
483A: *Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA*	0.000	88.744	438.376	298.623	-	298.623	42.549	10.326	10.071	10.743	Continuing	Continuing

Project MDAP/MAIS Code: 496

A. Mission Description and Budget Item Justification

DoD Healthcare Management System Modernization (DHMSM) Program:

• DHMSM will acquire, deploy, and implement an electronic health record (EHR) system that replaces the DoD legacy MHS inpatient and outpatient EHR systems. 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 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 all DoD operational environments.

• DHMSM will be executed to deliver uniform information management options across both garrison and theater environments. DHMSM will focus on the replacement of inpatient and outpatient systems, and will encompass deployment of the enterprise EHR to fixed facilities as well as expeditionary components.

• 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:

o Clinical workflow and provider clinical decision support;
o Capture, maintain, use, protect, preserve and share health data and information;
o 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
o Analysis and management of health information from multiple perspectives to include population health, military medical readiness, clinical quality, disease management, and medical research.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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*

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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: DoD Healthcare Mgmt System Modernization (DHMSM) Program	88.744	438.376	298.623

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 2015 Accomplishments:

• Completed the following Acquisition Documentation (Acquisition Strategy, Business Case, Engineering Master Plan, Cost and Benefit Analysis, Test Strategy, and Deployment and Training Change Management Plan (DTCM) and Life Cycle Supportability Plan [LCSP]) to support Authority to Proceed (ATP) for Contract Award. Approximately 1300 comments were received by the DHMSM Program Office and favorably adjudicated to ensure that each and every comment received in reference to the acquisition documents was given the proper consideration in reaching an agreed upon resolution thereby delivering quality acquisition documents that were thoroughly vetted and reviewed internally and by external organizations.

• Achieved Authority to Proceed (ATP) for contract award. Several steps were taken to achieve ATP for contract award, to include but not limited too; IOC Site Readiness Report to include preparation activities, change management, training, deployment, and testing to indicate the sites are ready for Contractor interaction; Reconciliation Report of functional workflow analysis, led by clinical champions, indicating alignment of capabilities with operations; report indicating GAL readiness and ability to proceed with testing; funding confirmation to prepare and process individual task orders; update Acquisition Documents as required; and infrastructure plans (WAN, LAN, Base Network, Standard Computing Devices), to include funding and schedule status."

• The DHMSM Test & Evaluation (T&E) staff developed and coordinated the T&E Master Plan (TEMP). The TEMP summarizes the phases of the DHMSM T&E, along with the approach and activities to be performed in each. The TEMP constituted a pre-Contract Award mandate, which DOT&E and DASD(DT&E) approved as required.

• Completion of the DHMSM PMO led source selection activities for the acquisition of a commercial electronic health record (EHR) solution. Solicitation N00039-14-R-0018 was released on 25 August 2014 utilizing full and open competition. Proposals

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
were received on 31 October 2014. Proposal evaluations were conducted in FY15 Q1 through Q3. A competitive range was established on 18 February 2015 and an award made on 29 July 2015. . • Contract N00039-15-D-0044 was awarded on 29 July 2015 with a total ordering ceiling of $4.3 billion. The award was made without protest. The total ordering period is up to 10 years if all options are exercised and award terms earned. The indefinite delivery, indefinite quantity (IDIQ) contract is for the acquisition of a commercial EHR solution and associated engineering, testing, deployment, and sustainment activities. The contract contains both cost reimbursement and fixed price line items with various incentive fee structures. This contract will improve current interoperability among DoD, the VA and private sector health- care providers and enable each to access and update health records. Contract is based on protocols established by the Office of the National Coordinator for Health Information Technology and the DoD/VA interagency program office. • Pre-award, the CMIO team was integrally involved, working with DHA, in the development and validation of 9 test and evaluation scenarios (BPM Phase 1) and 498 enterprise workflows (BPM Phase 2). Five of the 9 scenarios will be used for test and evaluation, while the other four are completely mapped to Cerner and Henry Schein workflows that will be used in test and evaluation. The 498 enterprise workflows have been mapped to the Cerner and Henry Schein workflows that will be used to configure the model build. The BPM phase 1 and 2 effort was instrumental to shorten the time to complete the review of over 644 Cerner and Henry Schein workflows, and contributed to a more comprehensive set of test and evaluation scenarios. • Pre-award, the Change Management team developed a draft Change Management strategy and Issue Resolution and Change Control Process (IRCCP). This effort provided the foundation for the Change Management Plan and the Change Control Process that is in use today, and continues to provide a roadmap for change management activities within the scope of the DHMSM contract. • Initiated development and configuration of Government Approved Laboratories for testing of the DHMSM EHR. The Fixed Facility Government-Approved Laboratory (GAL) is sited in a warehouse complex owned by GSA in Auburn, WA. Captured baseline equipment and medical device requirements from both clinical subject matter experts and the solution providers in order to outfit the FF GAL, which included infrastructure upgrades; power, telephone system, wired network, non-infrastructure items; tables, chairs, desks, computers, and various types of test equipment such as medical devices (physiological monitors, automated pharmacy systems, etc.) and peripheral devices (barcode scanners, wristband and label printers, etc.). The Operational Medicine (OM) GAL is sited at Fort Detrick, MD and has been set up to include a number of powered and environmentally conditioned Alaska shelters to include the addition of network and telephone system infrastructure and additional power handling capability. Coordinated with DISA and DHA Infrastructure technicians to provision commercial and military communication circuits in both			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
GALS. Directed the activities to ensure the cybersecurity infrastructure in the GALs mirrored the production environment to ensure a realistic test and evaluation atmosphere. The OM GAL will be transitioned to the Joint Operati onal Medicine Information Systems (JOMIS) Program Office in FY16 and JOMIS will complete the outfitting and equipping process in coordination with DHMSM and will support the testing of the DHMSM EHR. • Initialized Independent Verification and Validation (IV&V) planning activities and team. The IV&V team began staffing up following the award of the DHMSM EHR contract. The first major activity for the team was development of the Integrated Test and Evaluation Plan (ITEP), which describes all activities included in, or required for, the execution of the DHMSM Developmental Test and Evaluation (DT&E) program. During DT&E, the IV&V team will plan, perform, and analyze testing in order to assure that the EHR solution suits the needs of DoD, is fully functional in the DoD environment, and to provide an objective assessment of products and processes associated with the usage of the EHR. ***FY 2016 Plans:*** • Initial Design Review/Final Requirements Review. • Formal (or Final) Design Review/Test Readiness Review. • System Verification Review/Operational Test Readiness Review. • Configuration & Integration Test. • Developmental Test & Evaluation. • Training for Subject Matter Experts. • Limited Fielding Training. • Installed at Initial Operational Capability Sites. • Continue Configuration and Integration of solution in testing environment. • Continue Independent Verification and Validation (IV&V). ***FY 2017 Plans:*** • Finalize Operational Test & Evaluation. • Finalize Operational Readiness Review. • Full Initial Operation Capability (IOC) Fielding Training. • Onsite support. • IOC Declaration. • Full Deployment Decision ATP			
Accomplishments/Planned Programs Subtotals	88.744	438.376	298.623

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, PE 0807787: *DoD Healthcare Management Systems*	56.986	89.188	129.969	-	129.969	203.725	246.122	317.228	340.071	Continuing	Continuing
• BA-3, PE 0807787: *Information Technology Development and Sustainment - DoD Healthcare Management System Modernization*	0.000	0.000	29.468	-	29.468	499.193	547.160	532.476	474.888	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: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	0.000	0.000	11.000	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	0.000	11.000	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: PB 2017 Defense Health Agency	Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	0.000	11.000	0.000	-	0.000
Current President's Budget	0.000	11.000	0.000	-	0.000
Total Adjustments	0.000	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			

Change Summary Explanation

FY 2015: No change.

FY 2016: No change.

FY 2017: No change.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
458A: *DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)*	0.000	0.000	11.000	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 2015	FY 2016	FY 2017
Title: Defense Medical Information Exchange (DMIX) Program	0.000	11.000	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 2015 Accomplishments: No programmed funding under this initiative.			
FY 2016 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
• Continue to support the DMLSS Regionalization and data consolidation, reducing the deployed footprint (Hardware and Software), without compromise in performance and quality. • Complete successful testing to achieve a Full Deployment Decision (FDD) in July 2016 • Sustain the DMIX Data Exchange Services and sustain the DMIX Viewer post Full Deployment Decision (FDD). • Deploy Release 4, which will address the remainder of the Military Health System Functional Advisory Committee (MHS FAC) approved viewer requirements to include scanned documents and radiologic images. • Operational Test and "red team" assessment on DMIX Release 3. • Support DoD Healthcare Management System Modernization (DHMSM) Initial Operational Capability (IOC) integration and testing in Pacific Northwest. Upgrade data terminology service to support objective data sharing architecture and DHMSM. • Continue on-board Private Sector Partners (Heath Information Exchange partners) and Enhanced Multi-Service Markets (eMSMs) in order to maximize the ability to view a more robust patient medical history. • Quarterly updates of DoD/VA Interagency Program Office (IPO) certified data maps. • Inclusion of required HAIMS non-radiological images capability. • Upgrade of VLER DoD functionality limited to eHealth Exchange Gateway, GUI, C32/C62 generation. • Sustainment of current VLER Health 2.1.X Baseline. • Sunset VLER Health and JEHRI to the "new" DMIX Data Exchange Service. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	11.000	0.000

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA-1, 0807788HP: *DoD Medical Information Exchange and Interoperability*	0.000	59.743	57.268	-	57.268	45.305	46.951	47.892	48.703	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: PB 2017 Defense Health Agency		Date: February 2016
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)*

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.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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)*

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
Total Program Element	0.000	0.000	0.000	22.140	-	22.140	22.180	22.619	23.071	23.532	Continuing	Continuing
447A: *Joint Operational Medicine Information System (JOMIS)*	0.000	0.000	0.000	22.140	-	22.140	22.180	22.619	23.071	23.532	Continuing	Continuing

A. Mission Description and Budget Item Justification

Resources the deployment and related sustainment of Medical Information Technology (IT) software to provide integrated medical care information across multiple echelons of operational medicine to combatant commanders in support of time-sensitive decisions for successful operations. JOMIS integrates the medical care information under a joint concept of operations that assists the medical commander/command surgeon to maximize delivery of combat medical care with field medical operations in functional areas including: command and control, medical logistics, patient regulation and evacuation, medical/threat intelligence, healthcare delivery, manpower/training, and medical capabilities assessment and sustainability analysis. Once fully fielded, JOMIS will support the new Electronic Health Record (EHR) and legacy operational medical systems not being replaced by the new EHR. JOMIS will also modernize, integrate, and or replace non-EHR functionality as required by the Capability Development Document.

B. Program Change Summary ($ in Millions)	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	0.000	0.000	0.000	-	0.000
Current President's Budget	0.000	0.000	22.140	-	22.140
Total Adjustments	0.000	0.000	22.140	-	22.140
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			
• New Joint Operational Medicine Information System (JOMIS) Program	0.000	0.000	22.140	-	22.140

Change Summary Explanation

FY 2015: No change.

FY 2016: No change.

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605025-Theater Medical Information Program - Joint (TMIP-J) (-$22.140 million) to DHP RDT&E PE 0605045-Joint Operational Medicine Information System (JOMIS) (+$22.140 million).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
447A: *Joint Operational Medicine Information System (JOMIS)*	0.000	0.000	0.000	22.140	-	22.140	22.180	22.619	23.071	23.532	Continuing	Continuing

A. Mission Description and Budget Item Justification

The mission of the Department of Defense (DoD) Joint Operational Medicine Information Systems (JOMIS) program is to modernize, deploy, and sustain the DoD's operational medicine systems. Maintaining complete and accurate medical records while in an operational environment is an essential part of patient care management. Practitioners need access to up-to-date patient health records to ensure that relevant data is accessible and interoperable to support effective clinical decision making and clinical information management. The approved Concepts of Operations for healthcare delivery requires end-to-end capability and covers garrison and expeditionary environments. As such, USD (AT&L) and USD (P&R) have directed that the DoD Healthcare Management System Modernization (DHMSM) program provide the electronic health record (EHR) core for all health IT platforms – both garrison and theater.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Joint Operational Medicine Information System (JOMIS)	0.000	0.000	22.140

Description: The JOMIS Program will provide modernized capabilities that are operationally suitable, survivable, and effective and satisfy capability gaps identified in the JOMIS Capability Development Document (CDD). The acquisition strategy (AS) is constructed around the following two integrated efforts:
1. Operational Medicine Software Release 1: The JOMIS Program will develop the next operational medicine software release, based on the results of the Product Evaluation. The software release will first replace several of the existing capability components within TMIP-J today.
2. New Requirements for Operational Medicine: The JOMIS acquisition of any new capabilities will be designed to meet evolving operational requirements captured in an emerging Capabilities Development Document (CDD). Contract award for the JOMIS acquisition is currently planned for FY 2017

FY 2015 Accomplishments:
No funding programmed for Joint Operational Medicine Information System (JOMIS).

FY 2016 Plans:
Funding programmed under Operational Medicine Support initiative Program Element 0605025DHA pending start up of JOMIS.

FY 2017 Plans:
- Complete Test and Evaluation for Release I
- Initiate Full Operational Test & Evaluation for Services
- Authorization-To-Proceed (ATP) milestones for JOMIS Release I

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
• Initial Fielding ATP to achieve Initial Operational Capabililty (IOC) for Release I • Contract award ATP for JOMIS future releases			
Accomplishments/Planned Programs Subtotals	0.000	0.000	22.140

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• BA1 0807726DHA: *JOMIS*	0.000	0.000	11.136	-	11.136	25.428	31.592	37.721	44.187	Continuing	Continuing
• BA3 0807726DHA: *JOMIS*	0.000	0.000	2.413	-	2.413	77.358	75.688	75.150	73.605	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: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	56.728	25.383	16.787	17.954	-	17.954	15.219	20.295	21.589	22.022	Continuing	Continuing
375A: *GDF-Medical Products and Support System Development*	33.042	11.585	15.051	17.180	-	17.180	14.464	19.421	20.654	21.068	Continuing	Continuing
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	23.686	1.648	0.855	0.774	-	0.774	0.755	0.874	0.935	0.954	Continuing	Continuing
500A: *CSI - Congressional Special Interests*	0.000	12.150	0.881	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 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 (FDA) 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 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, 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 Defense Health Program (DHP) sponsored research. The JPCs supported by this PE include medical simulation and information sciences (JPC-1) and combat casualty care (JPC-6). The work includes development and demonstration of medical modeling and simulation systems for training/education/treatment, and medical system development and demonstration. 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: PB 2017 Defense Health Agency	Date: February 2016
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 Restore Core Research Funding Reduction. Because of the CSI annual structure, out-year funding is not programmed.

B. Program Change Summary ($ in Millions)	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	14.499	15.906	20.094	-	20.094
Current President's Budget	25.383	16.787	17.954	-	17.954
Total Adjustments	10.884	0.881	-2.140	-	-2.140
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	12.150	0.881			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.266	-			
• Rebalance Joint Program Committees	-	-	-0.913	-	-0.913
• Restore USUHS Breast, GYN, and Prostate Cancer Centers of Excellence	-	-	-0.633	-	-0.633
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-0.594	-	-0.594

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Project: 500A: *CSI - Congressional Special Interests*		
Congressional Add: *465A – Program Increase: Restore Core Research Funding Reduction (GDF)*	5.000	0.800
Congressional Add: *475A – Program Increase: Restore Core Research Funding Reduction (Army)*	7.150	0.081
Congressional Add Subtotals for Project: 500A	12.150	0.881
Congressional Add Totals for all Projects	12.150	0.881

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support Systems Development (-$1.266 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$1.266 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (+$12.150 million).

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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 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).

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).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
375A: *GDF-Medical Products and Support System Development*	33.042	11.585	15.051	17.180	-	17.180	14.464	19.421	20.654	21.068	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 following Joint Program Committees (JPCs). 1- Medical Simulation and Information Sciences (JPC-1). This 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 JPC-1, 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-Military Operational Medicine (JPC-5). This JPC supports the testing and evaluation of real-time physiological status monitoring in order to provide actionable patient information. 3- Combat Casualty Care (JPC-6). This JPC seeks FDA approval of methods, drugs and devices through human clinical trials. Within JPC-6, 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD)	11.585	15.051	17.180
Description: GDF-Medical Products and Support Systems Development (GDF-MPSSD): 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 point of care devices.			
FY 2015 Accomplishments: Within JPC-1, the Medical Simulation task area released an intramural solicitation/made awards for research to perform validation studies comparing commercially available or advanced prototype simulation systems and currently used live tissue training models. This work supported the advanced development of technologies to reduce and refine the use of live tissue for training. The intramural Tactical Combat Casualty Care Training for Readiness project modified and integrated existing technologies to improve training for non-medical personnel/Combat Life-Savers and started effectiveness studies to evaluate the technologies versus previous models/tools.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Within JPC-6, related to hemorrhage, clinical trials were initiated in support of a Spray Dried Plasma product. These included dosing studies and studies assessing safety and effectiveness. In addition, documentation was prepared to begin the FDA approval process. Within the Neurotrauma area, development continued on the lightweight Biomarker Assessment for Neurotrauma Diagnosis and Improved Triage System (BANDITS), a portable device to diagnose mild, moderate and severe TBI. In addition, advanced development continued on two platforms for measuring biomarkers for TBI. ***FY 2016 Plans:*** Within JPC-1, the Medical Simulation task is continuing evaluations of the effectiveness of commercially available or advanced prototype simulation systems and currently used live tissue training models. This work supports the advanced development of technologies to reduce and refine the use of live tissue for training. In addition, evaluate data and provide recommendations to refine and re-evaluate commercially available simulator products. Within JPC-6, related to hemorrhage, the Spray Dried Plasma product is scheduled for a Milestone B decision on the Spray Dried Plasma product and planning will begin on clinical trials to confirm safety and effectiveness of the product in diverse populations. Within the Neurotrauma area, the BrainScope clinical sites will complete final close-out activities and perform data analysis. Advanced development will continue on two platforms for measuring biomarkers for TBI. ***FY 2017 Plans:*** Within JPC-1, the Medical Simulation task will perform functional, specification and tolerance testing of Beta prototypes and curricula processes through anatomically correct and responsive simulation systems with the intent of transitioning to the pre-manufacturing stage. Within JPC-5, military operational medicine will sponsor end-user field testing to validate a system-on-a-chip ultra-low power physiologic status monitoring system that integrates refined algorithms into actionable real-time physiological status health information. Within JPC-6, clinical trials confirm safety and effectiveness in diverse populations will begin for the Spray Dried Plasma product. In addition, Neurotrauma will prepare for Milestone C decision, and FDA approval related to platforms for measuring biomarkers for TBI.			
Accomplishments/Planned Programs Subtotals	11.585	15.051	17.180

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	23.686	1.648	0.855	0.774	-	0.774	0.755	0.874	0.935	0.954	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Army, the Hyperbaric Oxygen Therapy (HBO2) clinical trials will focus on research for development of treatment modalities using HBO2 for chronic post-concussion syndrome (PCS) after mild TBI. HBO2 human clinical trials are 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. Four HBO2 study sites are established within the Military Health System. Each of the research sites consists 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 changing trailer.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Hyperbaric Oxygen Therapy Clinical Trial (Army)	1.648	0.855	0.774
Description: 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 2015 Accomplishments:*** Prepared final clinical report on study which described initial findings related to the HBO2 therapy. Continued evaluation of radiologic and physiological biomarker technology, and began 6 month and 12 month subject follow-ups. Completed one of three on-going HBO2 clinical trials in various phases of execution. Continued enrollment to establish a database to document the effects of HBO2 treatment on normal healthy participants. Completed recruitment and participant surveys for long-term follow-up study of HBO2 subjects, and began analyzing survey responses. ***FY 2016 Plans:*** Complete two on-going HBO2 clinical trials. Submit final reports and manuscripts. Complete enrollment, begin data analysis, and establish a database to document the effects of HBO2 treatment on normal healthy participants. Complete evaluation of radiologic and physiological biomarker technology, and on-line 6 month and 12 month subject follow-ups. ***FY 2017 Plans:*** Will prepare final reports on two clinical trials. Will consolidate and format HBO2 data from three different HBO2 studies for inclusion into the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system.			
Accomplishments/Planned Programs Subtotals	1.648	0.855	0.774

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

Off-label use of an existing technology. The product is a knowledge product, with initial results to affect TBI treatment policy/reimbursement policy. Decision to pursue FDA registration will be made as part of a formal acquisition decision after the initial results are reviewed.

E. Performance Metrics

The HBO2 Program Management Office Integrated Product Team monitors performance of contracts through review of monthly, yearly and final progress reports to ensure that milestones are being met, deliverables will be transitioned on schedule and within budget and in accordance with DOD Instruction 5000.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
500A: *CSI - Congressional Special Interests*	0.000	12.150	0.881	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2015 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 2015	FY 2016
Congressional Add: 465A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2015 Accomplishments:*** FY 2015 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). ***FY 2016 Plans:*** 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).	5.000	0.800
Congressional Add: 475A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2015 Accomplishments:*** FY 2015 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). ***FY 2016 Plans:*** 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).	7.150	0.081
Congressional Adds Subtotals	12.150	0.881

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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*

E. Performance Metrics

N/A

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
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*							
COST ($ in Millions)	**Prior Years**	**FY 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	111.229	57.108	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
470A: *Small Business Innovation Research (SBIR) (Army)*	111.229	50.186	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	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 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 Defense Health Program (DHP), Research, Development, Test and Evaluation (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: PB 2017 Defense Health Agency					Date: February 2016
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**
Previous President's Budget	0.000	0.000	0.000	-	0.000
Current President's Budget	57.108	0.000	0.000	-	0.000
Total Adjustments	57.108	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	57.108	-			

Change Summary Explanation

FY 2015: Realignment to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+ $57.108 million) from the following DHP PEs:
DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (-$0.247 million);
DHP RDT&E, PE 0601117-Basic Operational Medical Research Sciences (-$0.654 million);
DHP RDT&E, PE 0602115-Applied Biomedical Technology (-$4.179 million);
DHP RDT&E, PE 0602787-Medical Technology (AFRRI) (-$0.096 million);
DHP RDT&E, PE 0603002-Advanced Technology (AFRRI) (-$0.024 million)
DHP RDT&E, PE 0603115-Medical Technology Development (-$19.731 million);
DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (-$8.523 million);
DHP RDT&E, PE 0605013-Information Technology Development (-$1.409 million);
DHP RDT&E, PE 0605023-Integrated Electronic Record (iEHR) (-$13.054 million);
DHP RDT&E, PE 0605025-Theater Medical Information Program - Joint (TMIP-J) (-$0.639 million);
DHP RDT&E, PE 0605026-DoD Healthcare Management System Modernization (DHMSM) (-$2.650 million)
DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (-$1.266 million);
DHP RDT&E, PE 0606105-Medical Program-Wide Activities (-$3.322 million);
DHP RDT&E, PE 0607100-Medical Products and Capabilities Enhancement Activities (-$1.316 million).

FY 2016: No Change.

FY 2017: No Change.

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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*

FY 2017: No Change.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
470A: *Small Business Innovation Research (SBIR) (Army)*	111.229	50.186	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The DHP SBIR Program participates in the first (FY.1) of three (FY.1, FY.2, and FY.3) DoD SBIR Solicitations. 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 Defense Health Program (DHP) sponsored research. DHP 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 the Defense Health Agency (DHA) Research, Development, and Acquisition (RDA) Directorate SBIR Program Manager (PM) and personnel from the supporting USAMRMC offices . Approved DHP SBIR topics are published in the FY.1 DoD SBIR Solicitation. 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 RDA Directorate SBIR PM. 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 2015	FY 2016	FY 2017
Title: Small Business Innovation Research (SBIR) Program	50.186	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 FY15 research area topics sought for proposals. ***FY 2015 Accomplishments:*** For FY 2015, sixteen DHP SBIR topics were developed for the 2015.1 DoD SBIR Solicitation. Funding for each topic was based on the technical merits of the proposals submitted. Topics included: 2015.1 DHP SBIR Topic DHP15-001 - Lateral Canthotomy and Cantholysis Training System. This DHP SBIR initiative funded research to develop a simulation-based system to provide psychomotor skills training to advanced health care providers in the performance of a Lateral Canthotomy and Cantholysis (LCC) procedure, a method of preserving eyesight. This effort solicited a total of nine SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by May 2016.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
2015.1 DHP SBIR Topic DHP15-002 - Mobile Virtual Interactive Presence Capability for Combat Casualty Care. This DHP SBIR initiative funded research to develop and demonstrate video overlay capability of virtual augmented reality technology, also known as VIPAAR, on a mobile Android Smart device (also known as an End User Device (EUD)) over a military tactical network. A medic at the point of injury will use the built-in EUD camera to transmit the image of the casualty to a forward Medical Treatment Facility (MTF), like a Battalion Aid Station (BAS). The mobile VIPAAR technology will allow a Medical Officer, at the MTF to see on his EUD or capable computer exactly what a medic sees at the point of injury, and then the Medical Officer can introduce his hands into the virtual field. This effort solicited a total of thirteen SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by September 2015. 2015.1 DHP SBIR Topic DHP15-003 - Virtual Medical Concierge Application. This DHP SBIR initiative funded research to demonstrate a prototype medical concierge application that will improve patient, employee, and visitor engagement with Military Health System Military Treatment Facilities (MTFs). Pilot the prototype at Walter Reed National Military Medical Center (WRNMMC). This effort solicited a total of twenty-seven SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by September 2015. 2015.1 DHP SBIR Topic DHP15-004 - Methodologies and Tools for Securing Medical Device Systems in Integrated Clinical Environments (ICE). This DHP SBIR initiative funded research to develop a toolset for analyzing the security properties of interconnected medical devices in an Integrated Clinical Environment (ICE). This effort solicited a total of eight SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by September 2015. 2015.1 DHP SBIR Topic DHP15-005 - Methodologies and Techniques for Balancing Usability and Security for Medical Devices in an Integrated Clinical Environment. This DHP SBIR initiative funded research to Research and develop new controls for securing in an integrated clinical environment from malicious threats, which minimizes impacts on clinical workflows and usability, and promotes patient safety using a model-based approach. This effort solicited a total of six SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of two Phase I proposals were selected under this topic. Awards will be made by September 2015.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
2015.1 DHP SBIR Topic DHP15-006 - Rapid Detection of Borrelia burgdorferi (Lyme disease) from Ticks. This DHP SBIR initiative funded research to a sensitive, specific, rapid, portable, field friendly assay to determine whether a tick or pool of ticks is infected with the Borrelia burgdorferi bacterium, the causative agent for Lyme disease. This effort solicited a total of twenty-five SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by September 2015.			
2015.1 DHP SBIR Topic DHP15-007 - Small Molecule to Combat Multidrug-Resistant Bacteria. This DHP SBIR initiative funded research to develop a small molecule to target at least one of the, but preferably multiple, multidrug-resistant bacteria that pose the greatest threat to military populations, specifically methicillin-resistant Staphylococcus aureus (MRSA), Acinetobacter baumannii, Enterobacter species (Escherichia coli and Klebsiella pneumoniae), and Pseudomonas aeruginosa (1). The small molecule may be (a) an antibiotic that is bacteriostatic or bactericidal in nature but not susceptible to currently known antibiotic resistance mechanisms or (b) a molecule that, when given in combination, improves the effectiveness of an existing antibiotic(s) by preventing the antibiotic from being inactivated. Such a small molecule would ideally be amenable to incorporation into a wound dressing material, or other delivery system. This effort solicited a total of nineteen SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by September 2015.			
2015.1 DHP SBIR Topic DHP15-008 - Predictive Capability for Infectious Diseases. This DHP SBIR initiative funded research to demonstrate a prototype system that will successfully predict the incidence of human infectious disease. In this context, "predict" is defined as approaches aiming to anticipate the likelihood that a specific infectious disease threat will emerge in the human population; whereas "forecast" refers to approaches that aim to project the likely progression of, and impact of specific mitigation measures on, the trajectory of infectious disease outbreaks. This effort solicited a total of six SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of two Phase I proposals were selected under this topic. Awards will be made by September 2015.			
2015.1 DHP SBIR Topic DHP15-009 - Ultimate Passive Dosimeter. This DHP SBIR initiative funded research to develop a non-invasive, wearable passive dosimeter that can be stored indefinitely until analysis is required. The ideal product would be able to measure chronic exposures (several days to weeks) of exposure to sub-acute levels of hazardous chemicals in the spectrum of military environments. The intent is to provide a broad screening process for a wide-range of hazards for exposure documentation			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
to gases, volatile and semi-volatile organics, as well as to substances that may need to be captured and analyzed by a variety of different mechanisms such as respirable aerosols. This effort solicited a total of eight SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by May 2016. 2015.1 DHP SBIR Topic DHP15-010 - Oxygen Separation from Air to Provide Supplemental Oxygen for Injured Soldiers. This DHP SBIR initiative funded research to develop and demonstrate new techniques to separate/enrich oxygen from air using minimal power to provide supplemental oxygen for injured soldiers under field conditions. This effort solicited a total of seventeen SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by May 2016. 2015.1 DHP SBIR Topic DHP15-011 - Modeling and Simulation of the Blood Platelet Storage Lesion. This DHP SBIR initiative funded research to demonstrate that a kinetic pathway model of blood platelet physiology and biochemistry can be used to simulate the deleterious effects of storage upon isolated platelets within 5-7 days, and to develop a prototype program or a commercially viable software product for improved blood product storage. This effort solicited a total of one SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of one Phase I proposals were selected under this topic. Awards will be made by September 2015. 2015.1 DHP SBIR Topic DHP15-012 - Real-Time Small-Volume Blood Sampling and Analysis for Coagulopathy of Trauma Analytes. This DHP SBIR initiative funded research to develop a biosensor technology capable of measuring specific analytes in blood, continuously, in real-time. The biosensor must be able to measure multiple analytes that are relevant to coagulopathy of trauma and related phenomenon (e.g. therapeutic agents and protein biomarkers). This effort solicited a total of eighteen SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by September 2015. 2015.1 DHP SBIR Topic DHP15-013 - Optimization of Cryoprotectants, Cryotherapeutics, and Protocols for Cryopreservation of Large Tissue Systems. This DHP SBIR initiative funded research for development of novel cryoprotectants, cryotherapeutics,			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
and cryopreservation protocols that will permit clinically effective banking of large complex vascularized composite tissues such as vital organs and limbs. This effort solicited a total of fifteen SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by September 2015. 2015.1 DHP SBIR Topic DHP15-014 - Optimal Rewarming Solutions for Cryopreserved Tissue Systems. This DHP SBIR initiative funded research to develop a capability to solve one of the remaining barriers towards true banking of organs and vascularized composite tissues – optimal rewarming methods of large cryopreserved tissues. This effort solicited a total of eight SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by September 2015. 2015.1 DHP SBIR Topic DHP15-015 - Objective Measurement Tool For Detection and Monitoring of Noise-Induced Hearing Loss. This DHP SBIR initiative funded research to develop an objective measurement tool for the detection of noise-induced hearing loss and a smart algorithm for monitoring. This effort solicited a total of eight SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of two Phase I proposals were selected under this topic. Awards will be made by September 2015. 2015.1 DHP SBIR Topic DHP15-016 - Novel Intraocular Visualization Tool. This DHP SBIR initiative funded research to develop a novel intraocular visualization tool to improve surgical outcomes following complex ocular trauma. This effort solicited a total of four SBIR Phase I proposals. In FY 2015, proposals were accepted through the 2015.1 DoD SBIR Solicitation pre-released in December 2014. Proposals were received in February 2015 followed by Technical Evaluation Team evaluations in March 2015. Phase I proposal selections were announced in May 2015. A total of three Phase I proposals were selected under this topic. Awards will be made by September 2015. ***FY 2016 Plans:*** No funding programmed. The DHP SBIR program is funded in the year of execution. ***FY 2017 Plans:*** No funding programmed. The DHP SBIR program is funded in the year of execution.			
Accomplishments/Planned Programs Subtotals	50.186	0.000	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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 FDA 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
470B: *Small Business Technology Transfer (STTR) Program*	-	6.922	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 DHP STTR Program can participate in any of the three (FY.A, FY.B, and FY.C) DoD STTR Solicitations. The process begins with a call for topics to the JPCs. DHP STTR topics are submitted directly to 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 Defense Health Agency (DHA) Research, Development, and Acquisition (RDA) Directorate STTR PM and personnel from the supporting USAMRMC offices. Approved DHP STTR topics are published in the DoD STTR Solicitation. 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 RDA Directorate STTR PM. 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 2015	FY 2016	FY 2017
Title: Small Business Technology Transfer (STTR) Program	6.922	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 2015 Accomplishments: For FY 2015 (DHP STTR 15.B), two topics were developed for the 2015.B DoD STTR Solicitation. Funding for each topic was based on the merits of responses to solicitations. Topics included: (1) Develop and/or evaluate a simple and efficient blood purification/extraction technology to selectively remove anti-A / anti-B antibodies from donor plasma resulting in the production of universal plasma; and			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
(2) Investigate and validate alternative approaches for wound healing such as laser and lightwave treatments. ***FY 2016 Plans:*** No funding programmed. The DHP STTR program is funded in the year of execution. ***FY 2017 Plans:*** No funding programmed. The DHP STTR program is funded in the year of execution.			
Accomplishments/Planned Programs Subtotals	6.922	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 FDA 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: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	155.364	38.052	57.807	58.410	-	58.410	69.191	63.755	67.219	68.563	Continuing	Continuing
305T: *USAMRIID IO&T (Army)*	66.576	7.328	20.027	2.915	-	2.915	13.708	0.455	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)*	31.031	4.567	0.103	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
401A: *CONUS Laboratory Support Clinical Infrastructure (Army)*	14.777	4.460	4.975	5.064	-	5.064	5.155	5.253	5.358	5.465	Continuing	Continuing
432A: *OCONUS Laboratory Infrastructure Support (Army)*	16.870	10.791	12.487	11.502	-	11.502	11.419	13.218	14.144	14.427	Continuing	Continuing
433A: *NMRC Biological Defense Research Directorate (BDRD) (Navy)*	7.055	3.273	3.975	2.148	-	2.148	2.968	3.109	5.163	5.266	Continuing	Continuing
442A: *USARIEM Pike's Peak IO&T (Army)*	0.186	0.000	0.000	0.234	-	0.234	0.000	0.000	0.000	0.000	Continuing	Continuing
600A: *CSI - Congressional Special Interests*	0.000	5.967	16.240	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
494A: *Medical Development (Lab Support) (Navy)*	0.000	0.000	0.000	36.547	-	36.547	35.941	41.720	42.554	43.405	Continuing	Continuing
376A: *GDF - Medical Program-Wide Activities*	0.000	1.666	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 (CONUS) and outside the continental US (OCONUS) laboratories and clinical trial sites; work is done in collaboration with DoD Military Treatment Facilities (MTFs). 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. Areas of research interest are closely aligned with the Army Medical Research and Materiel Command's Program Area Directorates. 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 (RDT&E) 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: PB 2017 Defense Health Agency	Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	38.075	41.567	25.156	-	25.156
Current President's Budget	38.052	57.807	58.410	-	58.410
Total Adjustments	-0.023	16.240	33.254	-	33.254
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	5.967	16.240			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-2.668	-			
• SBIR/STTR Transfer	-3.322	-			
• Realignment of the Medical Development Laboratory Support Program	-	-	38.211	-	38.211
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-5.191	-	-5.191
• Initial Outfitting and Transition (IO&T) Pike's Peak	-	-	0.234	-	0.234

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Project: 600A: *CSI - Congressional Special Interests*		
Congressional Add: *476A – Program Increase: Restore Core Research Funding Reduction (Army)*	5.071	1.476
Congressional Add: *466A - GDF-Restore Core Medical Program-Wide Activities (Army)*	0.000	11.100
Congressional Add: *476C – Program Increase: Restore Core Research Funding Reduction (Navy)*	0.896	3.664
Congressional Add Subtotals for Project: 600A	5.967	16.240

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Congressional Add Totals for all Projects	5.967	16.240

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0606105-Medical Program-Wide Activities (-$3.332 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+ $3.332 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0606105-Medical Program-Wide Activities (+$5.967 million).

FY 2016: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0606105-Medical Program-Wide Activities (+$16.240 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
305T: *USAMRIID IO&T (Army)*	66.576	7.328	20.027	2.915	-	2.915	13.708	0.455	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 2015	FY 2016	FY 2017
Title: USAMRIID IO&T (Army)	7.328	20.027	2.915
Description: US Army Medical Research Institute of Infectious Diseases in Fort Detrick, Maryland, initial outfitting and transition (IO&T) costs associated with military construction.			
FY 2015 Accomplishments: The FY 2015 USAMRIID IO&T program reflected the phased requirements based on construction progress as the building is turned over in two Beneficial Occupancy Date (BOD) phases. IO equipment purchased for FY 2015 fiscal year were equipment listings based on delivery lead time, building placement, installation, and bona-fide need criteria. FY 2015 transition costs were the incremental fiscal year requirements for operations that supported this multi-year MILC0N project. Funds provided personnel, travel, planning and acquisition support, research operations planning, and equipment planning.			
FY 2016 Plans: The FY 2016 USAMRIID IO&T program reflects the phased requirements based on construction progress as the building is scheduled to reach Phase 1 BOD for safety and Center for Disease Control certifications. Remaining IO equipment are purchased from equipment listings based on delivery lead time, building placement, installation, and bona-fide need criteria. FY 2016 transition costs are the incremental fiscal year requirements for operations that support this multi-year MILC0N 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, increased phased dual occupancy costs of old and new sites, hazardous material movement, medical cleaning, etc.			
FY 2017 Plans: The FY 2017 USAMRIID IO&T program will reflect the phased requirements based on construction progress as the building is scheduled to reach BOD and will initiate inspection to receive safety and Center for Disease Control certifications. Funds will also be used to support initial relocation of personnel, equipment, and research products to the USAMRIID Replacement Facility.			
Accomplishments/Planned Programs Subtotals	7.328	20.027	2.915

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)	0.000	0.000	0.000
Description: Management support for research projects at Pacific Joint Information Technology Center (JITC). ***FY 2015 Accomplishments:*** Pacific JITC will maintain, utilize, and promote use of the Pacific JITC Integrated Test and Evaluation Center (ITEC) (IV & V) by government entities including the testing and integration of Department Warfighter projects within the SCIF laboratory. The Pacific JITC will continue to work with functional end users and Defense Health Agency sponsors to map proposals and initiatives critical to the Warfighter, address Joint Service capability gaps, and Department requirements. Future funding for operations and support will be Operations & Maintenance as a result of re-organization within Defense Health Agency. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 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: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
397T: *USAMRICD IO&T (Army)*	31.031	4.567	0.103	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding supports the IO&T costs associated with MILCON for the US Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, MD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: USAMRICD IO&T (Army)	4.567	0.103	0.000
Description: The US Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, Maryland, initial outfitting and transition costs associated with military construction. ***FY 2015 Accomplishments:*** The FY 2015 USAMRICD IO&T program reflected the phased requirements based on construction progress as the building nears completion. FY 2015 transition costs were the incremental fiscal year requirements for operations that support this multi-year MILCON project. Funds provided for health facilities planning personnel, outfitting, personnel transition and relocation, relocation of laboratory chemical agents, continued decommissioning characterization for chemical and radiological decontamination, phased dual occupancy costs of old and new sites, and any remaining commissioning and transition support. ***FY 2016 Plans:*** For FY 2016 the USAMRICD IO&T program reflects the final phased requirements based on construction progress as the building completes. FY 2016 transition costs reflect the incremental requirements for operations that support this multi-year MILCON project. Funds provide for health facilities planning personnel, continuing decommission characterization for chemical and radiological decontamination, and any remaining commissioning and transition costs. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	4.567	0.103	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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, 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
401A: *CONUS Laboratory Support Clinical Infrastructure (Army)*	14.777	4.460	4.975	5.064	-	5.064	5.155	5.253	5.358	5.465	Continuing	Continuing

A. Mission Description and Budget Item Justification

CONUS 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 RDT&E research funds.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: CONUS Laboratory Support Clinical Infrastructure (Army)	4.460	4.975	5.064

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 2015 Accomplishments:

Supported staff engaged in multiple clinical investigations and performed 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 were: 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. Unique outcomes associated with the funding: supported over 60 clinical investigations, submitted more than 25 external funding applications, established a Clinical Investigation Committee to review research protocols and provide research support services, formed a group to solicit collaborative research partnerships with non-federal organizations, created a funding opportunities database to match funding opportunities to MTF investigators and identify ways to improve submission competitiveness, and replaced research staff lost through staff reductions related to subsiding war efforts.

FY 2016 Plans:

Continue to provide 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,

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 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 2017 Plans:*** Will continue to provide support efforts for military 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 supported by the program will be: 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	4.460	4.975	5.064

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, 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
432A: *OCONUS Laboratory Infrastructure Support (Army)*	16.870	10.791	12.487	11.502	-	11.502	11.419	13.218	14.144	14.427	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 Unit-Kenya (USAMRU-K) in Nairobi, Kenya, the US Army Medical Research Unit-Georgia (USAMRU-G) in Tbilisi, Georgia, and the US Army Medical Component-Armed Forces Research Institute of Medical Sciences (USAMC-AFRIMS) in Bangkok, Thailand. USAMRU-G is the newest laboratory, and is being established to provide 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 2015	FY 2016	FY 2017
Title: OCONUS Laboratory Infrastructure Support (Army)	10.791	12.487	11.502

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 Armed Forces Research Institute of Medical Sciences (AFRIMS) in Bangkok, Thailand; the US Army Research Unit-Kenya (USAMRU-K) in Nairobi, Kenya; and the US Army Medical Research Unit-Georgia (USAMRU-G) in Tbilisi, Georgia.

FY 2015 Accomplishments:

Infrastructure funding costs for AFRIMS and USAMRU-K laboratories consisted of administration and infrastructure support, which supported medical research and development of products such as biologics, drugs, and protectants, technologies, and knowledge products to treat/prevent military-relevant endemic diseases. Infrastructure funding for the Republic of Georgia laboratory further facilitated the establishment of this unit, as directed by the DEPSECDEF. The Concept Plan (CONPLAN) and Table of Distribution and Allowances (TDA) for USAMRU-G are approved. Permanent military personnel began to phase in to the unit as well as hiring of local national personnel.

FY 2016 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Infrastructure funding costs for AFRIMS, USAMRU-K, and USAMRU-G laboratories consists 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. ***FY 2017 Plans:*** Infrastructure funding costs for AFRIMS, USAMRU-K, and USAMRU-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 include resource management, logistics, safety, information technology activities, salaries, utilities, maintenance, transportation, shipping, vehicle maintenance and generator fuel.			
Accomplishments/Planned Programs Subtotals	10.791	12.487	11.502

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 and Thailand, and a time-phased effort for establishment of the same in the Republic of Georgia.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
433A: *NMRC Biological Defense Research Directorate (BDRD) (Navy)*	7.055	3.273	3.975	2.148	-	2.148	2.968	3.109	5.163	5.266	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 2015	FY 2016	FY 2017
Title: NMRC Biological Defense Research Directorate (BDRD) (Navy)	3.273	3.975	2.148
Description: Biological Defense Research is a completely reimbursable program. The program is sustained by competitive acquisition of research funding. The research dollars cannot pay for the increased operational costs of the program. The complete reimbursable nature of the program requires additional sustained core funding for its operational costs. ***FY 2015 Accomplishments:*** Funding covered costs related to the Central Utility Plant, Entry Control Point Security Force, and other operational costs for maintenance, refuse, and custodial requirements. These support functions enabled BDRD to meet its mission to protect the Warfighter from biological threat agents through the development and distribution of BW (Biological Warfare) agent detection assays, therapeutics, forensic analysis, and operation of deployable BW agent detection labs. ***FY 2016 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 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.			
Accomplishments/Planned Programs Subtotals	3.273	3.975	2.148

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
442A: *USARIEM Pike's Peak IO&T (Army)*	0.186	0.000	0.000	0.234	-	0.234	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 MILCON for the US Army Research Institute of Environmental Medicine (USARIEM) at Pike's Peak, Colorado.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: USARIEM Pike's Peak IO&T (Army)	0.000	0.000	0.234
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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** Will support 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.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.234

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
600A: *CSI - Congressional Special Interests*	0.000	5.967	16.240	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) 0606105 - Medical Program-Wide Activities. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
Congressional Add: 476A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core initiatives in PE 0606105. Funds supported the CONUS Laboratory Clinical Infrastructure (Project 401A) and the OCONUS Laboratories (Project 432A). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core initiatives in PE 0606105. Funds supported the OCONUS Laboratories (Project 432A).	5.071	1.476
Congressional Add: 466A - GDF-Restore Core Medical Program-Wide Activities (Army) ***FY 2015 Accomplishments:*** No funding Programmed. ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0606105. Funds supported the GDF-Medical Program-Wide Activities (Project 466A).	0.000	11.100
Congressional Add: 476C – Program Increase: Restore Core Research Funding Reduction (Navy) ***FY 2015 Accomplishments:*** FY 2015 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). ***FY 2016 Plans:*** 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).	0.896	3.664
Congressional Adds Subtotals	5.967	16.240

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
494A: *Medical Development (Lab Support) (Navy)*	0.000	0.000	0.000	36.547	-	36.547	35.941	41.720	42.554	43.405	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 2015	FY 2016	FY 2017
Title: Medical Development (Lab Support) (Navy)	0.000	0.000	36.547
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 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** Per Memorandum of Agreement signed 7 AUG 2015, funding realigned from PE 0603115 to PE 0606105. 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	0.000	36.547

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

C. Other Program Funding Summary ($ in Millions)

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
376A: *GDF - Medical Program-Wide Activities*	0.000	1.666	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The goal of the Medical Program-Wide Activities is to provide funding for research infrastructure management support at select continental United States (CONUS) and outside the continental US (OCONUS) laboratories and clinical trial sites; work is done in collaboration with DoD Military Treatment Facilities (MTFs). 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 (RDT&E) 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 2015	FY 2016	FY 2017
Title: 376A: GDF – Medical Program-Wide Activities	1.666	0.000	0.000
FY 2015 Accomplishments: Funding provides for research infrastructure management support, sustainment of technical subject matter expertise, and the costs related to the initial outfitting and transition (IO&T) of research, development, test and evaluation (RDT&E) medical laboratories funded under multi-year military construction (MILCON) projects. These IO&T funds are designated as appropriations other than MILCON.			
FY 2016 Plans: No Funding Programmed.			
FY 2017 Plans: No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	1.666	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: PB 2017 Defense Health Agency		Date: February 2016
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*

E. Performance Metrics

N/A

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	37.420	16.413	17.356	14.998	-	14.998	14.938	18.214	19.819	20.215	Continuing	Continuing
377A: *GDF-Medical Products and Capabilities Enhancement Activities*	36.084	14.031	17.356	14.998	-	14.998	14.938	18.214	19.819	20.215	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*	0.000	2.382	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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**
Previous President's Budget	17.474	17.356	17.647	-	17.647
Current President's Budget	16.413	17.356	14.998	-	14.998
Total Adjustments	-1.061	0.000	-2.649	-	-2.649
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	2.382	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-2.127	-			
• SBIR/STTR Transfer	-1.316	-			
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-2.291	-	-2.291

• Realignment of the Breast, GYN and Prostate Cancer Centers of Excellence	-	-	-0.358	-	-0.358

Congressional Add Details ($ in Millions, and Includes General Reductions)

	FY 2015	FY 2016
Project: 700A: *CSI - Congressional Special Interests*		
Congressional Add: *467A – Program Increase: Restore Core Research Funding Reduction (GDF)*	2.382	0.000
Congressional Add Subtotals for Project: 700A	2.382	0.000
Congressional Add Totals for all Projects	2.382	0.000

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0607100-Medical Products and Capabilities Enhancement Activities (-$1.316 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$1.316 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0607100-Medical Products and Capabilities Enhancement Activities (+$2.382 million).

FY 2016: No Change.

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).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
377A: *GDF-Medical Products and Capabilities Enhancement Activities*	36.084	14.031	17.356	14.998	-	14.998	14.938	18.214	19.819	20.215	Continuing	Continuing

A. Mission Description and Budget Item Justification

The goal of the Medical Products and Capabilities Enhancement is to test, evaluate, and support enhancement of existing medical products and medically-related IT systems within the areas of medical simulation, infectious disease, tactical 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 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. The program structure provides a flexible and responsive mechanism to accomplish these objectives. A solicitation is released annually with two submission deadlines. Civilian and military intramural investigators are eligible to apply. 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 Joint Program Committees 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 for final approval.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: 377A: GDF – Medical Products and Capabilities Enhancement Activities	14.031	17.356	14.998
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 2015 Accomplishments: One hundred and four (104) proposals were received in response to the FY 2015 solicitation. Of these, 20 were selected for funding. For ongoing Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) managed efforts: Analyzed sensor characterization data of fielded blast sensor system; incorporated the results of mobility studies into an Operational Requirements-based Casualty Assessment model; implemented IT-system enhancements to the JTAPIC environment. For other funded efforts: Analyzed test data assessing the ability of Army Combat Uniforms treated with the insecticide permethrin to serve as a barrier to ticks and mosquitoes after extended periods of use; started project to determine the population prevalence of a form of CYP2D6, a drug-metabolizing enzyme which has been linked to malaria relapse following treatment with primaquine (a drug to treat malaria); began planning for a study to assess whether a current method of monitoring traumatic brain injury (TBI) patients may worsen clinical outcomes; initiated a study to retrospectively evaluate the effectiveness of the Defense and Veterans Brain Injury Center (DVBIC) Progressive Return to Activity Clinical Recommendation Tool for Service members following concussion/mild TBI;			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
investigated improved methods to detect acute kidney injury by comparing a commercially available device measuring injury specific biomarkers against the current standard of practice; began assessment of a marksmanship trainer, the Conflict Kinetics Gunfighting Gym as a potential tool/metric to measure neurocognitive status/mental performance; progressed testing on improved junctional and extremity tourniquets to stop excessive bleeding. ***FY 2016 Plans:*** Solicit, review, and make awards for intramural proposals consistent with the intent of Program Element 6.7. Funded efforts: Analyze 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 recommendations on primaquine use to treat malarial relapse; begin patient enrollment in study to assess whether a current method of monitoring TBI patients may worsen clinical outcomes; continue 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; 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; complete assessment on the use of a marksmanship trainer, the Conflict Kinetics Gunfighting Gym, as a potential tool/metric to measure neurocognitive status/mental performance; evaluate technologies designed to fabricate custom ear pieces for hearing protection; collect retrospective data and begin a prospective study evaluating the efficacy of a peripheral nerve block to correct heterotopic ossification, which can occur after battlefield injuries, severe burn injuries and following amputation; continue evaluations of junctional and extremity tourniquets to stop excessive bleeding. ***FY 2017 Plans:*** Will solicit, review, and make awards for intramural proposals consistent with the intent of Program Element 6.7. 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 begin 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 provide recommendations on the use of a marksmanship trainer, the Conflict Kinetics (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; will continue 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.			
Accomplishments/Planned Programs Subtotals	14.031	17.356	14.998

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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*

D. Acquisition Strategy

Integrate product improvements and enhancements resulting from funded efforts. Use post marketing studies and surveillance to survey impact.

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	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 2015	FY 2016	FY 2017
Title: AF Advanced Technology Development – Rapid Technology Transition	0.000	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 2015 Accomplishments:*** Acquisition strategy approved and contract awarded for the enhancement of the XSTAT-30 Advanced Junctional Non-Compressible Hemorrhage Control Agent product. ***FY 2016 Plans:*** 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	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.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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*

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
700A: *CSI - Congressional Special Interests*	0.000	2.382	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) 0607100 - Medical Products and Capabilities Enhancement Activities. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
Congressional Add: 467A – Program Increase: Restore Core Research Funding Reduction (GDF)	2.382	0.000
FY 2015 Accomplishments: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0607100. Funds supported development of product enhancements within the core program (Project 377A). ***FY 2016 Plans:*** No Funding Programmed.		
Congressional Adds Subtotals	2.382	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A