Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program											Date: February 2015	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115HP *I Medical Technology Development*							
COST ($ in Millions)	**Prior Years**	**FY 2014**	**FY 2015**	**FY 2016 Base**	**FY 2016 OCO**	**FY 2016 Total**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**Cost To Complete**	**Total Cost**
Total Program Element	1,370.321	1,109.743	1,201.188	231.051	-	231.051	250.488	267.321	265.167	267.228	Continuing	Continuing
300A: *CSI - Congressional Special Interests*	1,061.685	802.400	975.057	-	-	-	-	-	-	-	-	-
238C: *Enroute Care Research & Development (Budgeted) (AF)*	3.685	4.666	3.394	1.340	-	1.340	-	-	-	-	Continuing	Continuing
238D: *Core Enroute Care R&D - Clinical Translational Focus (AF)*	0.000	-	-	0.997	-	0.997	2.045	2.240	2.282	2.328	Continuing	Continuing
238E: *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	-	-	0.997	-	0.997	2.045	2.239	2.282	2.327	Continuing	Continuing
243A: *Medical Development (Lab Support) (Navy)*	61.968	35.074	34.378	37.580	-	37.580	38.211	40.942	41.720	42.554	Continuing	Continuing
247A: *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	0.000	0.200	-	2.060	-	2.060	2.064	1.548	-	-	Continuing	Continuing
247B: *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	0.000	0.425	-	1.040	-	1.040	1.135	1.238	-	-	Continuing	Continuing
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	2.646	3.694	2.280	1.700	-	1.700	-	-	-	-	Continuing	Continuing
284C: *Core Human Performance R&D - Clinical Translational Focus (AF)*	0.000	-	-	1.003	-	1.003	2.349	2.664	2.762	2.817	Continuing	Continuing
284D: *Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)*	0.000	-	-	1.002	-	1.002	2.348	2.663	2.761	2.816	Continuing	Continuing
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	8.146	6.851	1.983	-	-	-	-	-	-	-	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program										Date: February 2015		
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*							
285B: *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	0.000	-	-	0.929	-	0.929	1.147	1.350	1.360	1.387	Continuing	Continuing
285C: *Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	-	-	0.928	-	0.928	1.147	1.349	1.360	1.387	Continuing	Continuing
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	14.728	14.508	12.558	8.173	-	8.173	10.653	10.833	10.950	11.169	Continuing	Continuing
307C: *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	0.000	-	-	1.000	-	1.000	1.500	2.235	2.375	2.463	Continuing	Continuing
307D: *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	-	-	1.000	-	1.000	1.500	2.235	2.375	2.463	Continuing	Continuing
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	2.847	4.769	4.699	1.180	-	1.180	1.160	1.560	1.640	1.673	Continuing	Continuing
308C: *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	0.000	-	-	1.503	-	1.503	1.500	1.497	1.501	1.531	Continuing	Continuing
308D: *Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	-	-	1.502	-	1.502	1.499	1.497	1.500	1.530	Continuing	Continuing
309A: *Regenerative Medicine (USUHS)*	6.877	7.031	9.190	9.489	-	9.489	9.646	9.823	10.009	10.209	Continuing	Continuing
373A: *GDF - Medical Technology Development*	128.139	168.541	113.048	116.775	-	116.775	134.178	149.012	150.022	149.701	Continuing	Continuing
378A: *CoE-Breast Cancer Center of Excellence (Army)*	13.077	11.965	8.664	7.299	-	7.299	5.709	4.068	3.553	3.624	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program										Date: February 2015		
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*							
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	11.425	10.707	7.570	6.377	-	6.377	4.989	3.555	3.105	3.167	Continuing	Continuing
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	4.822	3.674	3.594	3.520	-	3.520	3.368	3.214	3.057	3.118	Continuing	Continuing
382A: *CoE-Pain Center of Excellence (Army)*	3.652	2.784	-	-	-	-	-	-	-	-	Continuing	Continuing
382B: *CoE-Pain Center of Excellence (USUHS)*	0.000	-	2.722	2.823	-	2.823	2.871	3.247	3.310	3.376	Continuing	Continuing
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	13.516	7.771	6.907	6.260	-	6.260	5.456	4.628	3.300	3.366	Continuing	Continuing
398A: *CoE-Neuroscience Center of Excellence (USUHS)*	1.822	1.857	-	-	-	-	-	-	-	-	-	-
429A: *Hard Body Armor Testing (Army)*	1.356	-	-	-	-	-	-	-	-	-	-	-
431A: *Underbody Blast Testing (Army)*	20.929	10.938	4.818	2.679	-	2.679	1.869	-	-	-	-	-
448A: *Military HIV Research Program (Army)*	0.000	6.663	5.773	6.589	-	6.589	6.702	7.579	7.722	7.877	Continuing	Continuing
830A: *Deployed Warfighter Protection (Army)*	9.001	5.225	4.553	5.306	-	5.306	5.397	6.105	6.221	6.345	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. Research in this program element (PE) is designed to address areas of interest to the Secretary of Defense related to Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of priority investments in science, technology, research, and development as stated in the Quadrennial Defense Review. Program development and execution is peer-reviewed and fully 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. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) funding. Research supported by this PE includes JPC-1: medical simulation, health informatics, JPC-2: wound infection prevention and management, antimicrobial countermeasures, diagnostic systems for infectious diseases, JPC-5: injury prevention and reduction, psychological health and resilience, physiological health, environmental health and protection, JPC-6: hemorrhage (bleeding) and resuscitation, neurotrauma (diagnosis

and treatment of brain injury), traumatic tissue injury, forward surgical intensive critical care, joint en route care, military medical photonics, and JPC-8: rehabilitation of neuro-musculoskeletal injuries, pain management, regenerative medicine, and sensory system traumatic injury, restoration and rehabilitation. 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, beginning in FY14, Military Human Immunodeficiency Virus (HIV) Research Program funding was transferred from the Army to the DHP. This project funds research 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, four 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 Gynecologic CoE (Army) focuses on characterizing the molecular alterations associated with benign and malignant gynecologic 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 gynecologic disease. The Cardiac Health CoE (Army) provides evidence-based personalized patient engagement approaches for comprehensive cardiac (pertaining to the heart) event prevention through education, outcomes research and technology tools, as well as molecular research to detect cardiovascular (CV) (pertaining to the heart and blood vessels) disease at an early stage to ultimately discover a signature for CV 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. The Pain CoE (Army) examines the relationship between acute (rapid onset and/or short course) and chronic (persistent or long-lasting, usually longer than 3 months) pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect this has throughout the continuum to rehabilitation and reintegration. In FY15, the Pain CoE funding line is transferred from Army to the Uniformed Services University of the Health Sciences (USUHS).

In FY14, DHP funded the following Congressional Special Interest (CSI) peer-reviewed directed research programs: Amyotrophic Lateral Sclerosis (ALS) (degenerative neuronal disorder that causes muscle weakness and atrophy throughout the body), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis (MS) (disease that affects the brain and the spinal cord and causes severe physical and mental complications), Cancer, Lung Cancer, Orthopedics Research, Spinal Cord Research, 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 Research, Reconstructive Transplant, Global HIV/AIDS Prevention, Tuberous Sclerosis Complex (rare multi-system genetic disease that causes growth of non-malignant tumors in the brain and other vital organs), Duchenne Muscular Dystrophy (gene mutation in boys that causes muscle degeneration

and eventual death). CSIs also included the following programs: Joint Warfighter Medical Research, Trauma Clinical Research Repository, Orthotics and Prosthetics Outcomes, and HIV/AIDS Program Increase. 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: Enroute 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 from theater to Landstuhl and from Landstuhl to CONUS. Therefore, the Enroute Care thrust area studies include optimal time for patient transport, cabin altitude, noise, vibration, and environmental issues affecting patient physiology on the aircraft, and the Human Performance thrust area compliments Enroute Care through its studies on medic and aircrew performance on long missions, as well as special operations forces performance. 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: Directed Energy, Occupational and Environmental Health, and Advanced Diagnostics/Therapeutics. 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, and the Pain 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. 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. Beginning in FY15, the Pain CoE funding line is transferred from Army to USUHS.

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program					Date: February 2015
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*		R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*			
B. Program Change Summary ($ in Millions)	**FY 2014**	**FY 2015**	**FY 2016 Base**	**FY 2016 OCO**	**FY 2016 Total**
Previous President's Budget	290.852	226.131	231.951	-	231.951
Current President's Budget	1,109.743	1,201.188	231.051	-	231.051
Total Adjustments	818.891	975.057	-0.900	-	-0.900
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	802.400	975.057			
• Congressional Directed Transfers	-	-			
• Reprogrammings	34.452	-			
• SBIR/STTR Transfer	-17.961	-			
• Program Increase in Support of the Global Health Security Agenda (GHSA) - Project 247	-	-	3.100	-	3.100
• Realignment - Project 307B	-	-	-4.000	-	-4.000

Congressional Add Details ($ in Millions, and Includes General Reductions)	**FY 2014**	**FY 2015**
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	6.000
Congressional Add: *296A - Bone Marrow Failure Disease Research*	3.200	3.200
Congressional Add: *310A - Ovarian Cancer Research*	20.000	20.000
Congressional Add: *328A - Multiple Sclerosis Research*	5.000	5.000
Congressional Add: *335A - Peer-Reviewed Cancer Research*	25.000	50.000
Congressional Add: *336A - Peer-Reviewed Lung Cancer Research*	10.500	10.500
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*	100.000	105.000
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

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603115HP *I Medical Technology Development*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2014	FY 2015
Congressional Add: *400A - Peer-Reviewed Medical Research*	200.000	247.500
Congressional Add: *417A - Peer-Reviewed Alzheimer Research*	12.000	12.000
Congressional Add: *439A - Joint Warfighter Medical Research*	65.000	30.000
Congressional Add: *452A - Peer-Reviewed Reconstructive Transplant Research*	15.000	15.000
Congressional Add: *453A - Trauma Clinical Research Repository*	5.000	-
Congressional Add: *454A - Orthotics and Prosthetics Outcomes Research*	10.000	10.000
Congressional Add: *456A - HIV/AIDS Program*	7.000	12.900
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: *459A - Peer-Reviewed Epilepsy Research*	-	7.500
Congressional Add: *474A – Program Increase: Restore Core Research Funding Reduction (Army)*	-	7.575
Congressional Add: *474B – Program Increase: Restore Core Research Funding Reduction (Navy)*	-	6.856
Congressional Add: *474C – Program Increase: Restore Core Research Funding Reduction (Air Force)*	-	10.228
Congressional Add: *474D – Program Increase: Restore Core Research Funding Reduction (USUHS)*	-	2.514
Congressional Add: *463A – Program Increase: Restore Core Research Funding Reduction (GDF)*	-	94.584
Congressional Add Subtotals for Project: 300A	802.400	975.057
Congressional Add Totals for all Projects	802.400	975.057

Change Summary Explanation

FY2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603115-Medical Technology Development (-$17.961 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+$17.961 million).

FY 2014: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0603115-Medical Technology Development (+$802.400 million).

FY 2015: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0603115-Medical Technology Development (+$975.057 million).

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603115HP *I Medical Technology Development*

FY2015: Transfer of Pain Center of Excellence (CoE) from Army DHP RDT&E, PE 0603115-Medical Development Technology Development (-$2.722 million) to USUHS DHP RDT&E, PE 0603115-Medical Development Technology Development (+$2.722 million).

FY 2015: Change Proposal to merge USUHS DHP RDT&E, PE 0603115-Medical Development Technology Development (+$1.533 million) Center of Excellence for Neuroscience with Regenerative Medicine.

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603115-Medical Technology Development (-$4.000 million) to DHP RDT&E PE 0604110-Medical Products Support and Advanced Concept Development (+$4.000 million).

FY2016: Realignment Global Health Security Agenda (GHSA) adjustment to DHP RDT&E, PE 0603115-Medical Technology Development (+$3.100 million).

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 300A / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
300A: *CSI - Congressional Special Interests*	1,061.685	802.400	975.057	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

In FY14, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY14 Congressionally-directed research is to stimulate innovative research through a competitive, peer-reviewed research program, and focused medical research at intramural and extramural research sites. Specific peer-reviewed research efforts include the following: Amyotrophic Lateral Sclerosis (ALS) (degenerative neuronal disorder that causes muscle weakness and atrophy throughout the body), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis, Cancer, Lung Cancer, Orthopedic Research, Spinal Cord Research, Vision, Traumatic Brain Injury and Psychological Health (TBI/PH), Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer Research, Joint Warfighter Medical Research, Reconstructive Transplant, Trauma Clinical Research Repository, Orthotics and Prosthetics Outcomes, HIV/AIDS, Global HIV/AIDS Prevention, Tuberous Sclerosis Complex (rare multi-system genetic disease that causes growth of non-malignant tumors in the brain and other vital organs), and Duchenne Muscular Dystrophy (gene mutation affecting boys that causes muscle degeneration and eventual death). Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research	7.500	7.500
FY 2014 Accomplishments: This Congressional Special Interest initiative provided funds for research in Amyotrophic Lateral Sclerosis (ALS) (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 offered in FY14, the Therapeutic Development Award and the Therapeutic Idea Award. Applications were received in August 2014 followed by scientific peer review in October 2014. Funding recommendations will be made at programmatic review in December 2014. Awards will be made by September 2015.		
FY 2015 Plans: This Congressional Special Interest research initiative is for Amyotrophic Lateral Sclerosis (ALS) Research.		
Congressional Add: 293A - Autism Research	6.000	6.000
FY 2014 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 has funded research at universities, hospitals, nonprofit and for-profit institutions,		

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
as well as private industry. Two award mechanisms were offered in FY14, the Clinical Trial Award and the Idea Development Award. Applications were received in October 2014 followed by scientific peer review in December 2014. Funding recommendations will be made at programmatic review in February 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Autism Research.		
Congressional Add: 296A - Bone Marrow Failure Disease Research ***FY 2014 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 FY14, applications were accepted through one funding opportunity, the Idea Development Award, released in March 2014. Applications were received in August 2014 followed by scientific peer review in October 2014. Funding recommendations will be made at programmatic review in January 2015. Award(s) will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Bone Marrow Failure Disease Research.	3.200	3.200
Congressional Add: 310A - Ovarian Cancer Research ***FY 2014 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 FY14 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. Six award mechanisms were offered: Pilot Award, Clinical Translational Leverage Award, Investigator-Initiated Award, the Ovarian Cancer Academy Awards recruiting the Academy Leadership and Early-Career Investigators, and the Ovarian Cancer Academy Collaborative Award. Application submission deadlines were in August 2014 and in January 2015 followed by scientific peer reviews in October 2014 and March 2015. Funding recommendations will be made at the programmatic reviews in December 2014 and April 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Ovarian Cancer Research.	20.000	20.000
Congressional Add: 328A - Multiple Sclerosis Research	5.000	5.000

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
FY 2014 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 development of MS), assessment, and treatment of MS. This year specific areas of MS research focus were not stipulated. A new mechanism, the Investigator Initiated Partnership Award was offered to encourage synergistic partnerships between clinicians and research scientists inside and outside the MS field that will accelerate the movement of promising ideas in MS into clinical applications. Applications were received in September 2014 followed by scientific peer review in November 2014. Funding recommendations will be made at programmatic review in January 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Multiple Sclerosis Research.		
Congressional Add: 335A - Peer-Reviewed Cancer Research ***FY 2014 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 significantly 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: blood cancers, cancers related to exposures to radiation (ionizing), colorectal cancer, genetic cancer research, kidney cancer, Listeria vaccine (bacterial-based vaccine) for 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 (extracranial solid cancer), pancreatic cancer, and pediatric brain tumors. Two award mechanisms to support these topic areas were released in April 2014: the Career Development Award and the Idea Award with Special Focus. Applications were received in September 2014 followed by scientific peer review in November 2014. Funding recommendations will be made at programmatic review in February 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Peer-Reviewed Cancer Research.	25.000	50.000
Congressional Add: 336A - Peer-Reviewed Lung Cancer Research ***FY 2014 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 is offering four award mechanisms in FY14: the Career Development, the Clinical Exploration, the Concept, and the Idea Development Awards. Applications were received in August and September 2014	10.500	10.500

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
followed by scientific peer review in October and November 2014. Funding recommendations will be made at programmatic review in January 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Peer-Reviewed Lung Cancer Research.		
Congressional Add: 337A - Peer-Reviewed Orthopedic Research ***FY 2014 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. Six award mechanisms are being offered in FY14: Clinical Trial Award, Clinical Trial Development Award, Idea Development Award, Outcomes Research Award, Translational Research Award, and Expansion Award. Applications were received in August and October 2014 followed by scientific peer review in December 2014. Funding recommendations will be made at programmatic review in February 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Peer-Reviewed Orthopedic Research.	30.000	30.000
Congressional Add: 338A - Peer-Reviewed Spinal Cord Research ***FY 2014 Accomplishments:*** This Congressional Special Interest research initiative supported Spinal Cord Injury (SCI) research. The FY14 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. Though the SCIRP supports groundbreaking research, all projects must demonstrate solid scientific rationale. The SCIRP has identified three Areas of Encouragement for the FY14 program. Pre-hospital, en route care, and early hospital management of SCI, development, validation, and timing of promising interventions to address consequences of SCI and to improve recovery and 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 is included in the application. In FY14 four award mechanisms were offered including: Clinical Trial, Investigator-Initiated Research, Qualitative Research and Translational Research Awards. Pre-applications were due in July 2014; invited full applications were due in	30.000	30.000

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
October 2014 followed by scientific peer review in December 2014. Funding recommendations will be made at programmatic review in February 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Peer-Reviewed Spinal Cord Research.		
Congressional Add: 339A - Peer-Reviewed Vision Research	10.000	10.000
FY 2014 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 traumatic brain injury (TBI) and diseases that, despite their different pathogenesis (mechanisms that occur during disease development), all have a common end result -- degeneration of the critical components of the eye and impairment or loss of vision. The results of this research are intended to be used for restoration and maintenance of visual function to ensure and sustain combat readiness. Basic, translational (conversion of findings in basic science to practical applications) 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. Critical areas of research include advances and improvements in: vision rehabilitation strategies and quality of life measures, vision restoration following traumatic injury, mitigation and treatment of traumatic injuries, treatment for war-related injuries and diseases to ocular structures and the visual system, treatment of visual dysfunction (abnormal functioning pertaining to the eyes) associated with TBI, and modeling and simulation of traumatic ocular injury. To meet the goals of the program, two award mechanisms supported vision research, the Translational Research and the Hypothesis Development Awards. Pre-applications were reviewed in November 2013, applications submitted in February 2014, the scientific peer review occurred in March 2014, and programmatic review was held in May 2014. Ten applications were recommended for funding and are currently being negotiated. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Peer-Reviewed Vision Research.		
Congressional Add: 352A - Traumatic Brain Injury/ Psychological Health Research	100.000	105.000
FY 2014 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 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 FY14 TBI/PH research program were to support projects aligned with the National Research Action Plan, address Congressional intent, enable significant research collaborations, and complement ongoing Department of Defense (DoD) efforts to ensure the mental health and readiness of our military forces by promoting a better		

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
standard of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In addition to service-requested nominations, individual Broad Agency Announcement applications, and promising ongoing studies, four program announcements (PAs) were released to solicit applications that address these priorities. The Psychological Health Research Award PA is intended to support both applied (preclinical) research and clinical trials within specific topic areas addressing the prevention and treatment of military-relevant psychological health issues. The Neurosensory and Rehabilitation Research Award PA Supports both applied (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 Investigative Treatments for TBI and PTSD Clinical Trial Award PA responds to Section 704 of the National Defense Authorization Act for Fiscal Year 2014 and supports investigational treatments (including diagnostic testing) of TBI and PTSD received by members of the Armed Forces in health care facilities other than military treatment facilities. The Community Partners in Mental Health Research Award PA responds to Section 706 of the National Defense Authorization Act for Fiscal Year 2013 by supporting research on the causes, development, and innovative treatment of mental health, substance use disorders, TBI, and suicide prevention in members of the National Guard and Reserves, their family members, and their caregivers. Application submission deadlines for the PAs are in November 2014, January 2015, and February 2015. Scientific peer reviews will be held in January and March 2015 followed by programmatic reviews in March and May 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Traumatic Brain Injury/ Psychological Health Research.		
Congressional Add: 380A - Peer-Reviewed Breast Cancer Research	120.000	120.000
FY 2014 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, three award mechanisms were developed to support meritorious breast cancer research: Breakthrough Award, Era of Hope Scholar Award, and Innovator Award.		

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
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. The Breakthrough Award was offered twice during this fiscal year. Program Announcements (PAs) were released in March and September 2014. Application submission deadlines were in May and August 2014 for the first PAs. Application submission deadlines for the second PAs will be in December 2014 and January 2015. Scientific peer review was held in July and October 2014 and will be held again in March 2015 followed by programmatic reviews in September 2014, December 2014, January 2015, May 2015, and June 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Peer-Reviewed Breast Cancer Research.		
Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research	80.000	80.000
FY 2014 Accomplishments: This Congressional Special Interest research is 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 development, genetics, imaging, mechanisms of resistance, survivorship and palliative care, therapy, and tumor and microenvironment biology. To meet these goals for FY14, the following twelve award mechanisms were developed: Biomarker Development Award, Clinical Exploration Award, Collaborative Undergraduate HBCU Student Summer Training Award, Exploration-Hypothesis Development Award, Health Disparity Research Award, Idea Development Award, Laboratory-Clinical Transition Award, Physician Research Training Award, Population Science Impact Award, Postdoctoral Research Training Award, Prostate Cancer Biospecimen Resource Site Award, and Synergistic Idea Development Award. All Program Announcements were released in May 2014. The applications for the Exploration-Hypothesis Development Award were received and scientifically peer reviewed in July 2014, and recommended for funding at programmatic review in October 2014. Applications for the remaining funding mechanisms were received in September 2014-October 2014, and will undergo scientific peer review in November 2014-December 2014. Funding recommendations for these		

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
mechanisms will be made at programmatic reviews in January 2015-February 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Peer-Reviewed Prostate Cancer Research.		
Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research ***FY 2014 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 FY14 through five award mechanisms: the Clinical Trial Award, the Innovative Treatment Evaluation Award, the Investigator-Initiated Research Award (IIRA), the Investigator-Initiated Research Expansion Award and a New Investigator Award. The IIRA included an option that encourages research focused on developing a consensus case definition for Gulf War Illness. Application submission deadlines are in September 2014 and January 2015 followed by scientific peer review in November 2014 and March 2015. Funding recommendations will be made at programmatic review in January 2015 and May 2015. Awards will be made by September 2015 ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Gulf War Illness Peer-Reviewed Research.	20.000	20.000
Congressional Add: 396A - Research in Alcohol and Substance Use Disorders ***FY 2014 Accomplishments:*** This Congressional Special Interest research effort on Research in Alcohol and Substance Use Disorders was a competitive program to create translational research addressing alcohol and substance abuse issues. The goal of the program was to identify and develop new medications to improve treatment outcomes for alcohol and substance use disorders, especially related to traumatic brain injury and post-traumatic stress disorder(PTSD), through organizing multidisciplinary, team-based research efforts to translate contemporary basic knowledge into enhanced clinical protocols. The projects will study the hypothesis that prior traumatic stress experience will increase drug and alcohol seeking and that systemic administration of certain medications decrease the impact of stress-related stimuli on drug and alcohol seeking in preclinical and clinical studies of patients with both PTSD/ Substance Use Disorder. Other funded areas of research included studies on PTSD and protecting degeneration of the nervous system against alcohol toxicity on the nerves	4.000	4.000

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
in order to determine the pathophysiologic significance (functional changes associated with disease or injury) following traumatic stress. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Research in Alcohol and Substance Use Disorders.		
Congressional Add: 400A - Peer-Reviewed Medical Research ***FY 2014 Accomplishments:*** This Congressional Special Interest initiative for the Peer Reviewed Medical Research Program continues 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 are required to address at least one of the following 25 Congressionally-directed topics: acupuncture, arthritis, chronic migraine and post-traumatic headache, congenital heart disease, DNA vaccine technology for post-exposure prophylaxis, dystonia, epilepsy, food allergies, fragile X syndrome, hereditary angioedema, illnesses related to radiation exposure, inflammatory bowel disease, interstitial cystitis, lupus, malaria, metabolic disease, neuroprosthetics (artificial extensions to the body that restore or improve function of the nervous system lost due to disease or injury), pancreatitis, polycystic kidney disease, post-traumatic osteoarthritis, psychotropic medications, respiratory health, rheumatoid arthritis, segmental bone defects (injuries in which a section of bone is completely shattered or absent), and tinnitus (perception of sound, such as ringing, when no actual sound is present). Five award mechanisms are being offered in FY14: 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 2014, scientific peer review was conducted in September 2014, and funding recommendations will be made during programmatic review in January 2015. For the remaining mechanisms, application receipt will occur in October and November 2014, peer review will be conducted in December 2014 and January 2015, and funding recommendations will be made during programmatic review in March 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Peer-Reviewed Medical Research.	200.000	247.500
Congressional Add: 417A - Peer-Reviewed Alzheimer Research ***FY 2014 Accomplishments:*** This Congressional Special Interest research program was to study Alzheimer's disease. The mission of the Peer Reviewed Alzheimer Research Program continued to be two-fold. The program sought to 1) build an integrated program devoted to understanding the association between Traumatic Brain Injury (TBI) and Alzheimer's disease (AD), and 2) reduce the burden on caregivers and individuals affected by TBI-AD symptoms, especially in the military community. The program offered three funding mechanisms	12.000	12.000

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
in order to meet the program's mission. These are the 1) Convergence Science Research Award (CSRA), 2) Quality of Life Research Award (QUAL), and 3) Military Risk Factors Research Award (MRFA). The focus areas for the FY14 CSRA mechanism were expanded to include research that examines the role of non-neuronal cells (cells of the brain other than neurons e.g., glia) in TBI/AD pathogenesis. The CSRA mechanism also continued to request for research applications on genomic and proteomic studies to investigate the linkages between TBI and AD. The FY14 QUAL mechanism is to fund research which explores technologies, tests, interventions, epidemiological studies, or devices with the potential to benefit individuals suffering from the symptoms of TBI or AD, while reducing caregiver burden. The MRFA mechanism is to facilitate high-impact, systematic, population-based research investigating the association between TBI and the subsequent development of AD. The FY14 Program Announcements were released in September of 2014, with pre-applications, full applications, peer review, and programmatic review thereafter. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Peer-Reviewed Alzheimer Research.		
Congressional Add: 439A - Joint Warfighter Medical Research	65.000	30.000
FY 2014 Accomplishments: The Joint Warfighter Medical Research Program (JWMRP) was intended 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 supported military medical research in medical training and health information sciences, military infectious diseases, military operational medicine, combat casualty care, radiation health effects, and clinical and rehabilitative medicine. For the FY14 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/ 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 external scientific peer review was completed in June 2014. The programmatic review was completed in August 2014 and 32 projects were recommended for funding. Award negotiations will be complete by the end of the third quarter of FY15. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Joint Warfighter Medical Research.		
Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research	15.000	15.000
FY 2014 Accomplishments: This Congressional Special Interest research initiative for Reconstructive Transplant Research (RTR) is to accelerate the movement of promising ideas in restorative transplantation into		

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
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. Proposals are due in October 2014, scientific peer review is planned for December 2014, and programmatic review will take place in February 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Peer-Reviewed Reconstructive Transplant Research.		
Congressional Add: 453A - Trauma Clinical Research Repository ***FY 2014 Accomplishments:*** This Congressional Special Interest research initiative studied the development of a Trauma Clinical Research Repository. The purpose of the repository is to capture data in theater for review and research on patient care and outcomes.	5.000	-
Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research ***FY 2014 Accomplishments:*** FY 2014 Accomplishments: This Congressional Special Interest research initiative was offered for the first time in FY14. It is intended to support research that evaluates the comparative effectiveness of and functional outcomes associated with prosthetic and orthotic 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 (conversion of findings in basic science to practical applications) 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 will be 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, have the potential to lead to new technology developments that can lead to improved prosthetic 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 is encouraged. Joint DoD-VA studies, including longitudinal outcome studies, are particularly sought. A Program Announcement was released in October 2014. A total of 109 pre-	10.000	10.000

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
applications were received as of the pre-application receipt deadline in November 2014. Invitations to submit a full application are scheduled to be released in December 2014, with an application submission deadline in January 2015. Peer review is currently scheduled for March 2015, with programmatic review set for April 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Orthotics and Prosthetics Outcomes Research.		
Congressional Add: 456A - HIV/AIDS Program ***FY 2014 Accomplishments:*** This Congressional Special Interest research initiative complements 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 2015 Plans:*** This Congressional Special Interest research initiative is forHIV/AIDS Program.	7.000	12.900
Congressional Add: 540A - Global HIV/AIDS Prevention (Navy) ***FY 2014 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 2014 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. The HIV/AIDS Prevention program provided technical assistance and resource support for 25 foreign defense	8.000	8.000

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
forces in FY 2013. Accomplishments included over 45,000 individuals that received testing and counseling services for HIV and received their test results; 29,752 military members and their dependents targeted with HIV prevention interventions; more than 1,100 health care workers successfully completed an in-service training program; and 2,893 pregnant women knew their HIV status based on testing and counseling services provided to them. Accomplishments for FY 2014 will be reported after the end of the 2014 fiscal year, once annual program result data is collected. Because of the CSI annual structure, out-year funding is not programmed. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Global HIV/AIDS Prevention.		
Congressional Add: 660A - Tuberous Sclerosis Complex (TSC) ***FY 2014 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 FY14 TSCRP encouraged applications that address vital program focus areas of Clinical Aspects of TSC, Personalization of Care and/or Optimization of Treatments. This research effort offered three award mechanisms to support TSC research: Idea Development, Exploration-Hypothesis Development, and Pilot Clinical Trial Awards. Applications were due July 2014, followed by scientific peer review in September 2014, and funding recommendations made at programmatic review in November 2014. Awards will be will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Tuberous Sclerosis Complex (TSC).	6.000	6.000
Congressional Add: 790A - Duchenne Muscular Dystrophy ***FY 2014 Accomplishments:*** This Congressional Special Interest initiative was for research focused on Duchenne Muscular Dystrophy (DMD) (gene mutations in dystrophin affecting approximately 1 in 3600 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. Within this context, this program encourages applications that address a number of focus areas including: 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 (characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or biological responses to a therapeutic intervention); 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 two award mechanisms were offered in 2014, the Investigator-	3.200	3.200

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
Initiated Research Award and the Therapeutic Idea Award. Applications were received in October 2014 with scientific peer review in January 2015 and programmatic review in March 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Duchenne Muscular Dystrophy.		
Congressional Add: 459A - Peer-Reviewed Epilepsy Research ***FY 2014 Accomplishments:*** No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is forPeer-Reviewed Epilepsy Research.	-	7.500
Congressional Add: 474A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2014 Accomplishments:*** No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology Development Program Element (PE) - 0603115.	-	7.575
Congressional Add: 474B – Program Increase: Restore Core Research Funding Reduction (Navy) ***FY 2014 Accomplishments:*** No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology Development Program Element (PE) - 0603115.	-	6.856
Congressional Add: 474C – Program Increase: Restore Core Research Funding Reduction (Air Force) ***FY 2014 Accomplishments:*** No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology Development Program Element (PE) - 0603115.	-	10.228
Congressional Add: 474D – Program Increase: Restore Core Research Funding Reduction (USUHS) ***FY 2014 Accomplishments:*** No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology Development Program Element (PE) - 0603115.	-	2.514
Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF)	-	94.584

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
FY 2014 Accomplishments: No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology Development Program Element (PE) - 0603115.		
Congressional Adds Subtotals	802.400	975.057

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 238C / *Enroute Care Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
238C: *Enroute Care Research & Development (Budgeted) (AF)*	3.685	4.666	3.394	1.340	-	1.340	-	-	-	-	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 2014	FY 2015	FY 2016
Title: Enroute Care Research & Development (Budgeted) (AF)	4.666	3.394	1.340

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 2014 Accomplishments:

Continued research to enhance the care of acutely injured AE trauma patients through projects assessing closed loop technology for autonomous control of oxygenation and ventilation. Continued research to improve AE trauma patient care through the development and assessment of continuous, real-time vital sign monitoring system. Continued research assessing the clinical effect of prolonged hypobaria during AE on TBI, how AE affects blood volume responsiveness, improve pain management during AE, and identify/mitigate factors impacting patient safety during AE. Continued study of optimal time to transport patients. Continued development of the multi-channel negative pressure wound treatment device and monitor FDA 510K process. Began swine study to investigate post AE effects on coagulation and inflammation. Began a retrospective study of the efficacy of cabin altitude restrictions on AE patients. Continued automation of CCATT patient record, perform operational test. Began development

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 238C / *Enroute Care Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
of en route care retrospective research database. Began investigating new research and development requirements based on results of prior studies and warfighter gap analyses. Completed Air Worthiness certification for simulator mannequin and initiated use on Aeromedical Evacuation (AE) and Critical Care Transport Team (CCATT) training flights – transitioned to the CCATT Pilot Unit. Continued research to enhance the care of acutely injured AE trauma patients though projects assessing closed loop technology for autonomous control of oxygenation and ventilation. Completed and archived miniaturized Extra Corporal Membrane Oxygenation (ECMO) device bovine study. Analyzed initial results of research assessing the clinical effect of prolonged hypobaria during AE on Traumatic Brain Injury (TBI), how AE affects blood volume responsiveness, pain assessment during AE, and factors impacting patient safety during AE. Began assessing how the transport of psychiatric patients impacts AE crew protocols. Continued research examining medical records of traumatically injured patients transported by Critical Care Air Transport Teams (CCATT). Conducted research prospectively characterizing the incidence and success of Life Saving Interventions (LSI) performed by combat medics during pre-hospital and en route care. Began research for identifying optimal time to transport patients to ensure best outcomes. Began investigations into advanced development options for AE material solutions: began testing for a portable electrical power source; began development of a negative pressure multi-channel negative pressure wound therapy device; awarded and initiated automation of the CCATT patient record (Form 3899L) onto a widely-accepted portable physiologic monitoring device; and supported Air Mobility Command (AMC) in prototype development for a replacement aircraft patient loading system. Spear-headed DoD Information Assurance Certification and Accreditation Program (DIACAP) for telemedicine capability of a physiologic monitoring device in support of AMC requirements, which will allow for transmission of aeromedical electronic medical information across DoD information platforms. Presented research findings in peer-reviewed journals and at national meetings. Completed study on the following: effects of AE on the injury response, including potential worsening of the systemic inflammatory response, increased susceptibility to infection, and secondary brain injury after traumatic brain injury; the effects of hypobaric hypoxia exposure on a crush muscle crush injury during air transport. Continue research to enhance the care of acutely injured AE trauma patients through projects assessing closed loop technology for autonomous control of oxygenation and ventilation. Continue research assessing the clinical effect of prolonged hypobaria during AE on TBI, how AE affects blood volume responsiveness, improve pain management during AE, and identify/mitigate factors impacting patient safety during AE. Continue to study optimal time to transport patients. Continue development of the multi-channel negative pressure wound treatment device and monitor FDA 510K process. Begin Began swine study to investigate post AE effects on coagulation and inflammation. Begin Began a retrospective study of the efficacy of cabin altitude restrictions on AE patients. Begin Began study to determine the effects of altitude on patients requiring ECMO system for respiratory support during transport. Continue automation of CCATT patient record, perform operational test. Begin Began development of en route care retrospective research database. Begin Began investigating new research and development requirements based on results of prior studies and warfighter gap analyses.			
FY 2015 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 238C / *Enroute Care Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Plan and test for transition of miniaturized Extra Corporal Membrane Oxygenation device to Air Mobility Command (AMC) for Aeromedical Evacuation (AE) and Combat Casualty Air Transport Team (CCATT) and lung team use on long flight missions. Monitor technology readiness level of closed loop ventilation and oxygenation. Analyze final results of research describing blood administration, analgesics used, and burn care provided during Critical Care Air Transport. Development of new clinical practice guidelines and validation of existing guidelines for CCATT. Evaluate and describe current en route care practices from point of injury to in-theatre military treatment facilities. Provide descriptive analysis of non-traumatically injured patients and the clinical care provided during transport out of theatre on CCATT. Analyze final results of research assessing the clinical effect of prolonged hypobaria during AE, how AE affects blood volume responsiveness, improving pain management during AE, and factors impacting patient safety during AE, and determine translational elements of completed research or need for further studies. Complete and transition automated CCATT patient record and multi-channel negative pressure wound therapy device to acquisition process. Analyze results of cabin altitude restriction retrospective study, which should lead to better evidence-based decision-making for when to fly low. Continue swine study to investigate post AE effects on coagulation and inflammation. Continue investigating new research and development requirements based on results of prior studies and warfighter gap analyses.			
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. 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.”			
Accomplishments/Planned Programs Subtotals	4.666	3.394	1.340

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
• BA-1, PE 0807714HP: *Other Consolidated Health Support*	13.049	13.441	13.844	-	13.844	14.259	14.655	-	-	Continuing	Continuing

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 238C / *Enroute Care Research & Development (Budgeted) (AF)*

D. Acquisition Strategy

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinatinons 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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 238D / *Core Enroute Care R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
238D: *Core Enroute Care R&D - Clinical Translational Focus (AF)*	-	-	-	0.997	-	0.997	2.045	2.240	2.282	2.328	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 2014	FY 2015	FY 2016
Title: Core Enroute Care R&D - Clinical Translational Focus (AF)	-	-	0.997

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 2014 Accomplishments:
No funding programmed.

FY 2015 Plans:
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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 238D / *Core Enroute Care R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
the ventilator registry will be used to define the requirements of a system to perform closed loop ventilation. Continue pursuing the AFMS strategic goal A1 to “Transform the En-route Care System” based on war fighter identified gaps and validated requirements. Begin and/or continue work that will improve mission effectiveness in the A2AD environment such as closed loop technologies and enabling capabilities leading to autonomous patient transport.”			
Accomplishments/Planned Programs Subtotals	-	-	0.997

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 238E / *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
238E: *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	-	-	-	0.997	-	0.997	2.045	2.239	2.282	2.327	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 2014	FY 2015	FY 2016
Title: Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)	-	-	0.997

Description: 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: 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 this the En-Route Patient Safety sub-project area will examine human factors considerations in en-route patient safety in order to develop new and enhance existing methods to mitigate risk in all en-route care environments.

FY 2014 Accomplishments:
No funding programmed.

FY 2015 Plans:
No funding programmed.

FY 2016 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *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 2014	FY 2015	FY 2016
Continue development of the en route care retrospective research database. Continue research to improve patient outcomes by providing advanced notification of resuscitation needs. Continue research to identify the effects of altitude preconditioning and also biomarkers as predictors of acute lung 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 investigating new research and development requirements based on results of prior studies and warfighter gap analyses. Continue closed loop interventions research and development.			
Accomplishments/Planned Programs Subtotals	-	-	0.997

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 243A / *Medical Development (Lab Support) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
243A: *Medical Development (Lab Support) (Navy)*	61.968	35.074	34.378	37.580	-	37.580	38.211	40.942	41.720	42.554	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, 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 2014	FY 2015	FY 2016
Title: Medical Development (Lab Support) (Navy)	35.074	34.378	37.580
Description: RDT&E funds for 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. Excludes military manpower and related costs, non-RDT&E base operating costs, and military construction costs, which are included in other appropriate programs.			
FY 2014 Accomplishments: Provided operating and miscellaneous support costs at BUMED research laboratories. Continued to provide support for 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. Additional Funding received will be used for 64 administrative civilian FTE's that had to be reprogrammed from the overhead account, due to new financial model. Funding will also be used for existing government inherent civilian vacancies that are not in the current manpower controls.			
FY 2015 Plans: 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 2016 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 243A / *Medical Development (Lab Support) (Navy)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
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.			
Accomplishments/Planned Programs Subtotals	35.074	34.378	37.580

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 247A / *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
247A: *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	-	0.200	-	2.060	-	2.060	2.064	1.548	-	-	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 2014	FY 2015	FY 2016
Title: Elimination of Malaria in Southeast Asia (CARB) (Navy)	0.200	-	2.060

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 2014 Accomplishments:
No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative.

FY 2015 Plans:
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 is to enhance the malaria surveillance in Vietnam, will be completed in FY14. The malaria surveillance system is being optimized to define exactly where transmission is occurring with novel mapping to support targeted

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 247A / *Elimination of Malaria in Southeast Asia (CARB) (Navy)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
interventions and the monitoring and evaluation of their impact. It will build upon existing funded projects, leveraging investments from the US Government, international partners and non-Government Agencies. In FY15, surveillance efforts started in 2014 will expand 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) has requested a cross-sectional study be conducted to determine the parasite carriage rate and proportion of drug-resistant parasites within the military. This study is 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 and leverage FY14 investments. 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.			
Accomplishments/Planned Programs Subtotals	0.200	-	2.060

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 247A / *Elimination of Malaria in Southeast Asia (CARB) (Navy)*

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 247B / *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
247B: *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	-	0.425	-	1.040	-	1.040	1.135	1.238	-	-	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. 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: Prevent Avoidable Epidemics; Detect Threats Early; and Respond Rapidly and Effectively to biological threats of international concern.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Mitigate the Global Impact of SepSis Through ACESO (CARB) (Navy)	0.425	-	1.040
Description: This project seeks to demonstrate that the impact of sepsis 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 2014 Accomplishments: No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative.			
FY 2015 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 247B / *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
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 will be 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 will support 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.			
Accomplishments/Planned Programs Subtotals	0.425	-	1.040

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 284B / *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	2.646	3.694	2.280	1.700	-	1.700	-	-	-	-	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 2014	FY 2015	FY 2016
Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)	3.694	2.280	1.700
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 2014 Accomplishments: Completed high altitude/U-2 pilot imaging and comparison baseline studies. Completed mountain altitude acclimatization research. Completed the study on risk and protective factors and social-occupational impairment among AF Special Operations Forces personnel. Assessed fatigue management using non-visual light stimulation. Expanded ongoing studies on understanding hypoxia, focusing on previously unidentified latent effects. Began initial evaluations of potential technologies capable of providing in-flight assessment of pilot physiological measures. Kick-off new study looking at acute MRI changes and time course of development secondary to hypobaric exposure in select AF physiology and pilot populations			
FY 2015 Plans: Complete high altitude/U-2 pilot imaging and comparison baseline studies. Complete the study on risk and protective factors and social-occupational impairment among AF Special Operations Forces personnel and evaluate some of the measures instituted as a result of this effort. Pursue human systems integration studies. Assess novel fatigue and cognitive management modalities.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 284B / *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Expand ongoing studies on understanding hypoxia, focusing on previously unidentified latent effects. Initiate Pilot Physiology and Cognitive Performance to determine physiological impacts during manned flight to determine mitigations needed to maintain / optimize performance. Perform development of fitness readiness algorithms to enhance AF personnel training and prevent injuries. ***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 magnify each other. Advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention.			
Accomplishments/Planned Programs Subtotals	3.694	2.280	1.700

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

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinatinons 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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 284C / *Core Human Performance R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
284C: *Core Human Performance R&D - Clinical Translational Focus (AF)*	-	-	-	1.003	-	1.003	2.349	2.664	2.762	2.817	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 2014	FY 2015	FY 2016
Title: Core Human Performance R&D - Clinical Translational Focus (AF)	-	-	1.003
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 2014 Accomplishments:*** No funding programmed. ***FY 2015 Plans:*** No funding programmed. ***FY 2016 Plans:*** Mature a comprehensive program working to define and mitigate the extreme physiological demands of higher altitudes to include decompression sickness and hypoxia. Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions magnify each other. Advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention.			
Accomplishments/Planned Programs Subtotals	-	-	1.003

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 284C / *Core Human Performance R&D - Clinical Translational Focus (AF)*

C. Other Program Funding Summary ($ in Millions)

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 284D / *Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
284D: *Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)*	-	-	-	1.002	-	1.002	2.348	2.663	2.761	2.816	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 2014	FY 2015	FY 2016
Title: Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)	-	-	1.002

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 2014 Accomplishments:
No funding programmed.

FY 2015 Plans:
No funding programmed.

FY 2016 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *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 2014	FY 2015	FY 2016
Continue assessment of in-flight pilot performance monitoring. Begin assessment of potential physiological measures capable of capturing physiological and cognitive state of AF pilot and operator personnel. Evaluate current / planned technologies employed in current generation aircraft against human performance limitations to address changes needed to technology or identify performance optimization techniques. Conclude efforts identifying the effects of combining over-the-counter stimulants with Modafinil, which may stimulate the need for further research. Apply results from high altitude and hypoxia studies to refine this line of research and potentially spur operational and training changes, and identify areas needed for further research. Implement plans to pursue human systems integration studies, focusing on identified gaps. Conduct operational based vision research.			
Accomplishments/Planned Programs Subtotals	-	-	1.002

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 285A / *Operational Medicine Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	8.146	6.851	1.983	-	-	-	-	-	-	-	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 2014	FY 2015	FY 2016
Title: Operational Medicine Research & Development (Air Force)	6.851	1.983	-

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 2014 Accomplishments:

Continued patient centered/personalized medicine research efforts related to autism and obesity. Aligned resources with academia and other health agencies to evaluate outcomes of standardized diabetes prevention initiatives, including online resources. Determined if medication therapy management program for patients with chronic pain at a large Military Treatment Facility reduced costs and improved outcomes. Evaluate personalized prevention and treatment efforts related to Patient-Centered Precision Care. Building on previous work, identified opportunities for advanced development of mobile health application technologies within the MHS for personalized disease prevention and management. Began evaluation of utilization and effectiveness of current AF mental health/family support programs for the purposes of identifying gaps and possible solutions to areas such as marital discord, family maltreatment, binge drinking, and suicide.

FY 2015 Plans:

Continue patient centered/personalized medicine research efforts related to autism and obesity. Align resources with academia and other health agencies to evaluate outcomes of standardized diabetes prevention initiatives, including online resources. Through intramural efforts, determine if a medication therapy management program for patients with chronic pain at a large Military Treatment Facility will reduce costs and improve outcomes. Evaluate personalized prevention and treatment efforts related

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 285A / *Operational Medicine Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
to Patient-Centered Precision Care. Building on previous work, identify opportunities for advanced development of mobile health application technologies within the MHS for personalized disease prevention and management. Begin evaluation of utilization and effectiveness of current AF mental health/family support programs for the purposes of identifying gaps and possible solutions to areas such as marital discord, family maltreatment, binge drinking, and suicide.Building on previous work, concentrate on the use of mobile health technologies to integrate evidenced-based solutions into clinical practice and the EHR to positively influence behavior and promote health. Further the work related to AF mental health/family support by pilot testing proposed solutions to specified issues in an effort to translate solutions into AFMS wide practice. Determine the timeliness of communication (information exchange) of clinical information and the effectiveness of communication processes to identify gaps or potential patient safety issues that may impact outcomes to include morbidity and mortality. Begin regenerative/reconstructive research to validate technologies for surgical reconstruction of service members with previously non-reconstructable injuries, and investigate devices for advanced wound healing. Continue evaluate personalized prevention and treatment efforts related to Patient-Centered Precision Care in the areas of chronic pain following traumatic brain injury, post-traumatic stress disorder, and substance abuse. ***FY 2016 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	6.851	1.983	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 285B / *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
285B: *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	-	-	-	0.929	-	0.929	1.147	1.350	1.360	1.387	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 2014	FY 2015	FY 2016
Title: Core Operational Medicine R&D - Clinical Translational Focus (AF)	-	-	0.929

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 2014 Accomplishments:
No funding programmed.

FY 2015 Plans:
No funding programmed.

FY 2016 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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 285B / *Core Operational Medicine R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
technologies for surgical reconstruction of service members with previously non-reconstructable injuries. Continue development in the areas of chronic pain following traumatic brain injury, post-traumatic stress disorder, and substance abuse.			
Accomplishments/Planned Programs Subtotals	-	-	0.929

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 285C / *Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
285C: *Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)*	-	-	-	0.928	-	0.928	1.147	1.349	1.360	1.387	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 2014	FY 2015	FY 2016
Title: Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)	-	-	0.928
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 2014 Accomplishments:*** No funding programmed. ***FY 2015 Plans:*** 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.			
Accomplishments/Planned Programs Subtotals	-	-	0.928

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 285C / *Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	14.728	14.508	12.558	8.173	-	8.173	10.653	10.833	10.950	11.169	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 2014	FY 2015	FY 2016
Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force)	14.508	12.558	8.173
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 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016

stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to detect and identify the USAF- and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need.

FY 2014 Accomplishments:

Tested miniaturized sensors to identify toxic breathing air and hypoxic aircrew. Initiated research and development for the integration and demonstration of advanced medical, physiological status sensors and exposure sensors in a laboratory environment to prepare them for aircraft integration. Delveloped a compact, insulated, leak-proof, laboratory-approved transport system for shipping food samples from remote locations to the laboratory. Developed prototype devices to detect and quantify lasers used to illuminate aircraft and qualify the health threat to aircrew. Analyzed methodologies and challenges associated with the establishment of a genome data repository for future implementation of genomic medicine. Continued 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. Developed extremely light weight and easy to use methodologies enabling Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Performed a comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed.

FY 2015 Plans:

Continue to engage with the Precision Care Advisory Panel (PCAP), a joint service committee to provide service-specific operational and policy guidance for the implementation of personalized medicine within the DoD. Initiated study to perform high-content, rapid throughput toxicology with pluripotent cells allowing for a rapid screening of possible threats in the aerospace environment.

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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
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.			
Accomplishments/Planned Programs Subtotals	14.508	12.558	8.173

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
307C: *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	-	-	-	1.000	-	1.000	1.500	2.235	2.375	2.463	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 2014	FY 2015	FY 2016
Title: Core Force Health Protection R&D - Clinical Translational Focus (AF)	-	-	1.000
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			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016

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

FY 2014 Accomplishments:
No funding programmed.

FY 2015 Plans:
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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
AFMS. Provide further analysis in educational interventions for the proper use of genetic testing within the AFMS. Research for pharmacogenomics for anti-depressents and pain medication within the AFMS. Analysis of methodologies and challenges associated with the establishment of an AFMS genome data repository for future implementation of genomic medicine. To augment capabilities for genomic research within the AFMS, the USAF will continue participation in National Human Genome Institute pharmacogenomic research projects. Continue to develop a high-content, rapid throughput toxicological capability with pluripotent cells allowing 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 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
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.			
Accomplishments/Planned Programs Subtotals	-	-	1.000

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *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 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
307D: *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	-	-	-	1.000	-	1.000	1.500	2.235	2.375	2.463	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 2014	FY 2015	FY 2016
Title: Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)	-	-	1.000

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 2014 Accomplishments:
No funding programmed.

FY 2015 Plans:
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. Develop and validate devices or methods that are extremely light

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *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 2014	FY 2015	FY 2016
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. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference.			
Accomplishments/Planned Programs Subtotals	-	-	1.000

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	2.847	4.769	4.699	1.180	-	1.180	1.160	1.560	1.640	1.673	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 2014	FY 2015	FY 2016
Title: Expeditionary Medicine Research & Development (Air Force)	4.769	4.699	1.180

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 2014 Accomplishments:

Transition the Trauma Specific Vascular Injury Shunt device, and proceed to fielding and procurement. Initiate research on therapeutic drugs given by first responders to slow body functions providing more time to transfer of seriously wounded to definitive care. Continue research on a novel technique for infection control of traumatic wounds, predicting blood needs using pre-hospital vital signs, and hemorrhagic shock resuscitation. Pursue additional research to mature the multi-channel negative pressure wound treatment system and continue to address advanced development issues. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Completed the FDA approval process for the Trauma Specific Vascular Injury Shunt (TS-VIS). Completed follow on studies evaluating applied predictive algorithms for the continuous non-invasive monitoring of patient status in order to predict actionable interventions. Evaluated clinical utility of prototype laser device

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
for hemorrhage control and tissue cutting and archived results for future inquiries. Transitioned Virtual Medical Trainer (09) software platform for preparing leaders and decision makers to hone communication and planning skills for interagency disaster response efforts. Completed testing of predictive algorithms in field-deployable burn diagnostic tool to ultimately improve long-term prognosis. Completed research on predicting oxygen needs based on clinical variables and testing novel techniques for infection control of traumatic wounds to include a bioelectric dressing and topical agent for antibiotic resistant bacteria. Continued studies for predicting blood needs using pre-hospital vital signs, development of portable sterilization technology for surgical instruments in remote setting. ***FY 2015 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. Complete research on coagulopathy, hemorrhagic shock resuscitation and other life-saving interventions (LSIs), and development of portable sterilization technology for surgical instruments in remote settings. Build on ongoing work with concentration on therapeutic interventions to sustain life through transfer to definitive care. Continue development of multi-channel negative pressure wound treatment system. Complete transitioning and fielding of TS-VIS via commercial or advanced development partners. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. ***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, 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.			
Accomplishments/Planned Programs Subtotals	4.769	4.699	1.180

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 308C / *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
308C: *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	-	-	-	1.503	-	1.503	1.500	1.497	1.501	1.531	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 2014	FY 2015	FY 2016
Title: Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)	-	-	1.503

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 2014 Accomplishments:
No funding programmed.

FY 2015 Plans:
No funding programmed.

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, rhabdomyolysis and ischemia-reperfusion injury. Transition multi-channel negative pressure wound treatment system to advanced development.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 308C / *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Support advanced development of TS-VIS if necessary. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics.			
Accomplishments/Planned Programs Subtotals	-	-	1.503

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 308D / *Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
308D: *Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)*	-	-	-	1.502	-	1.502	1.499	1.497	1.500	1.530	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 2014	FY 2015	FY 2016
Title: Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)	-	-	1.502
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 2014 Accomplishments:*** No Funding Programmed. ***FY 2015 Plans:*** 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 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.			
Accomplishments/Planned Programs Subtotals	-	-	1.502

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 308D / *Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 309A / *Regenerative Medicine (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
309A: *Regenerative Medicine (USUHS)*	6.877	7.031	9.190	9.489	-	9.489	9.646	9.823	10.009	10.209	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 2014	FY 2015	FY 2016
Title: Regenerative Medicine (USUHS)	7.031	9.190	9.489

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 over 104 research projects.

FY 2014 Accomplishments:

-Natural history studies are identifying relevant outcome measures across the spectrum of TBI and co-morbid psychological health issues. Military and civilian cohort studies are addressing the post-injury progression from hyper-acute through chronic stages. This hyper-acute imaging is revealing changes that occur within the first hours and days after injury, demonstrating the importance of early MRI to better diagnose brain injury.

-Under the Acute Studies Core, established productive clinical research program to address acute TBI injuries at Virginia Commonwealth University, Suburban Hospital and Washington Hospital Center that has resulted in recruitment of more than 300 participants into acute TBI studies with imaging. These early clinical interactions are also directly connected to longitudinal follow up at the NIH CC with potential for recruitment into other CNRM studies.

-Across the spectrum of TBI severity and times post-injury, 2,719 patients have enrolled in CNRM clinical research protocols through 2014.

-TBI clinical database has been implemented with policies for submission and sharing across CNRM investigators and institutions at USU, WRNMMC, and NIH, Importantly, the CNRM database is aligned with the Federal Interagency TBI Research (FITBIR) database.

-State-of-the-art neuropathological center established under Dr. Dan Perl with infrastructure for brain specimen acquisition, evaluation, storage, and distribution. This brain repository is the first dedicated to military service members.

-Advanced neuroimaging capabilities, including: acquisition of simultaneous human MRI and PET, improving diffusion imaging for clinical requirements, testing novel PET ligands for inflammation and neurodegeneration. The CNRM Siemens Biograph mMR

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
System was the second installed in a U.S. clinical setting and the first to scan a human patient using simultaneous MRI and PET. 771 subjects have been scanned through July 31,2014. -The Translational Imaging core continues to develop novel scanning protocols for rodent microPET, microCT, and 7T MR, especially as relevant to specialized needs for TBI pathologies and with consideration of comparison with the human scanning applications. -The Image Processing Core has implemented a database platform for managing the CNRM Imaging Repository with integration of the database with the Informatics database addressed following initial deployment. -CNRM researchers are detecting molecular biomarkers of inflammation and neurodegeneration, including auto-antibodies that persist in blood and allow identification of transient responses to central nervous system damage. The center is collaborating in the biomarkers component of the Chronic Effects of Neurotrauma Consortium, a multi-site Veterans Affairs and Defense Department effort. -Pre-clinical studies across multiple TBI models are identifying mechanisms of CNS damage and repair, including molecular and cellular substrates of neuroregeneration and neuroplasticity. The range of TBI models is particularly designed to address the spectrum of injury experienced by military service members. A state-of-the-art Advanced Blast Simulator is being used for pathological, imaging, and behavioral analyses. -Hosted the annual National Capital Area TBI Research Symposium with no registration fees. The symposium has brought together scientists from local institutions and organizations to network, exchange data and ideas, and advance TBI research and treatment. -CNRM research project information was uploaded into the Federal RePORTER database in spring 2014. This contribution now allows project information to be publicly available and easily searchable, thus paving the way for other Defense Department funding agencies to follow suit. -Through summer-2014, CNRM has published over 140 peer-reviewed publications. In addition, CNRM researchers have presented at numerous national and international conferences.			
FY 2015 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 FY15-16 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			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
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) Merge the research work of the Neuroscience Center of Excellence (MCNCoE)through development of research fellowship program. ***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 FY16-17funding; (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.			
Accomplishments/Planned Programs Subtotals	7.031	9.190	9.489

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
• BA-1, 0806721HP: *Uniformed Services University of the Health Sciences*	8.755	8.912	9.090	-	9.090	9.272	9.458	9.647	9.840	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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

E. Performance Metrics

Center for Neuroscience and Regenerative Medicine: In FY14 through FY16, 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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 373A / *GDF - Medical Technology Development*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
373A: *GDF - Medical Technology Development*	128.139	168.541	113.048	116.775	-	116.775	134.178	149.012	150.022	149.701	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. Research in this PE is designed to address the following: areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of priority investments in science, technology, research and development as stated in the Quadrennial Defense Review. Program development and execution is peer reviewed and fully 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. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program (DHP) Research Development Test and Evaluation (RDT&E) funding. Research supported by this PE includes(JPC-1): medical simulation, health informatics, (JPC-2): wound infection prevention and management, antimicrobial countermeasures, diagnostic systems for infectious diseases, (JPC-5): injury prevention and reduction, psychological health and resilience, physiological health, environmental health and protection, (JPC-6): hemorrhage (bleeding) and resuscitation, neurotrauma (diagnosis and treatment of brain injury), traumatic tissue injury, forward surgical intensive critical care, joint en route care, military medical photonics, and (JPC-8): rehabilitation of neuro-musculoskeletal injuries, pain management, regenerative medicine, and sensory system traumatic injury, restoration and rehabilitation. 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 2014	FY 2015	FY 2016
Title: GDF – Medical Technology Development	168.541	113.048	116.775
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 2014 Accomplishments: The medical simulation and information sciences research program conducted research in two primary research portfolios: Medical Simulation and Training, and Health Informatics and Information Technology. Medical simulation and training focused on research to support combat medic training and inform decisions regarding the reduction and refinement of live-tissue training. Began development of open-source virtual tissue advancement program to better understand the tissue characteristics needed to integrate into medical models for future simulations. Additional emphasis was placed on the technologies to teach and train effective team performance. Health informatics and information technology progressed in evaluating algorithms to provide nurses			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
with appropriate medical information to inform better decisions. Progress was also made in developing a test environment for electronic health records, allowing developers a robust environment to optimize products before launch to live systems. The military infectious diseases research program funded a multi-year, clinical study for development of an antibacterial drug against multiple drug resistant bacteria to mitigate hard to treat wound infections. A study in humans evaluated safety and effectiveness of a bacteriophage (viruses in bacteria) cocktail against Staphylococcus aureus (a drug-resistant bacteria) with the aim to develop novel skin and soft tissue infection treatment options. An additional study was initiated to reduce surgical site infection rates during complex combat-related wounds, which will help reduce the need for an extended course of systemic antibiotics, irrigation, and surgical debridement. Evaluated effectiveness to detect bacterial infections in wounds aimed to reduce excess empiric antibiotic use while awaiting conventional culture and susceptibility results. Research was initiated on the Next Generation Diagnostic Systems to detect malaria, dengue, and chikungunya. Military operational medicine research is grouped into four portfolios of injury prevention and reduction, psychological health and resilience, physiological health, and environmental health and protection. Injury prevention and reduction developed standards for low level, repetitive blast exposures during breaching (process used to force open closed and/or locked doors), developed performance and musculoskeletal health metrics (pertaining to muscle and bone health)for Warfighters in military training environments, and developed blast and auditory injury models to provide medical injury criteria. Psychological health and resilience evaluated behavioral interventions to treat alcohol and substance abuse, determined the feasibility of cognitive behavioral interventions (a type of therapy that focuses on examining the relationships among thoughts, feelings and behaviors) for the treatment of PTSD, evaluated interventions to build resiliency in military families and Warfighters, and initiated efforts to improve accurate suicide prevention screening and delivery of innovative peer leader-led suicide prevention interventions. Physiological health developed guidelines for nutritional supplementation to minimize injuries during initial military training and developed interventions for dietary and weight loss in Warfighters. Environmental health and performance measured health effects of chemical exposures (e.g., permethrin, an insecticide used to treat uniforms), measured biomarkers of pulmonary health (pertaining to the lungs) from exposures to toxic substances in the deployed environment to assess health and disease outcomes, and developed decision aids for managing thermal physiological strain. Combat casualty care is grouped into portfolios for hemorrhage and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, joint enroute care, and military medical photonics. Hemorrhage and resuscitation developed platelet-derived agents to stop bleeding and modulate immune inflammatory responses, foams to stop internal bleeding, enhanced storage of red blood cells, and low blood volume resuscitation techniques, conducted a clinical trial on using plasma first during resuscitation of traumatic hemorrhages, developed techniques to reduce pathogens in whole blood. Neurotrauma developed biomarkers (substance, such as a protein, indicating the presence of a condition) for TBI, developed a prehospital drug for TBI, conducted a clinical trial on Eye-Trac technology to diagnose and assess TBI, conducted a pivotal clinical trial			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
on a preconditioning oral nutritional supplement as a possible treatment for TBI, and developed neuroassessment protocols to standardize treatment practice. Traumatic tissue injury conducted research on face restoration, orthopedic advances, and compartment syndrome (a life-threatening condition resulting from injury wherein increased pressure occurs within legs or arms). The traumatic tissue injury program also conducted outcomes-related research on genitourinary injury (a follow-up to the basic epidemiology study done earlier, looking at long-term outcomes). Forward surgical intensive critical care conducted a clinical study on a technique using an endovascular (minimally invasive surgery to access regions of the body via major blood vessels) balloon to open occlusions of the aorta in severe pelvic fracture and hemorrhagic shock cases, started research on intensive care interventions with the Joint Trauma System in the US Army Institute of Surgical Research. Joint enroute care conducted research on real-time, physiologic monitoring across the battle space, supported a patient immobilization effort, developed improved field management and safe air transport of patients with head and spine injuries, developed a joint-force aeromedical transport litter immobilization and stabilization platform, and developed an enroute care registry to better track best practices. Military medical photonics developed optical technology for military medical applications with a focus on the use of lasers, spectroscopy, and imaging. Clinical and rehabilitative medicine advanced studies in neuromusculoskeletal injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Extended studies started in FY13 to support development and preclinical evaluations of candidate technologies for restoration and rehabilitation strategies and medical products. In pain management, a pain outcome registry tracked treatment results and created evidence-based clinical guidelines for care, studied the effects of a treatment drug on burn pain, and evaluated methadone and opioid related adverse events. Regenerative medicine initiated clinical studies for craniomaxillofacial intraoral defects (defects within the mouth), immunomodulation strategies for composite tissue allotransplantation (hand and face transplantation), and skin coverage following burn injury. Sensory systems research started studies to verify the prevalence of central auditory processing disorders in blast-exposed Warfighters, evaluated computerized oculomotor (eye motion) vision screening to expedite the diagnosis of TBI-related oculomotor dysfunctions in a military population, studied the effects of blast exposure on the hearing of deployed Navy and Marine Corps personnel, and evaluated cochlear implants to improve hearing for active duty Service members.			
FY 2015 Plans: Medical simulation and information sciences research program is focusing in two primary research portfolios: Medical simulation and training and health informatics and information technology. Medical simulation and training research is continuing 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 is supporting 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 is releasing a program announcement focused on effective ways to interface with technology			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
through gestures or facial expressions that are military medically relevant. Medical simulation is also requesting proposals via a program announcement to improve en route care methods for wounded Service members. This effort is focusing on the hand-offs and transfer of patients between providers. Military infectious diseases research is focusing on Next Generation Diagnostic Systems, where we are developing the capability to detect malaria, dengue, and chikungunya, achieving TRL-6, and preparing for transition to Medical Countermeasure Systems for advanced development. Evaluating the results of the bacteriophage (a group of viruses that infect and replicate in bacteria) study to determine a path forward. The wound infection prevention and management host/pathogen biomarker project, for detection of bacterial infection in wounds, is completing laboratory and initial animal studies to confirm its effectiveness and accuracy. Under antimicrobial countermeasures, clinical studies continue 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. Several studies are also being initiated for the development of antibacterial or other wound infection prevention strategies. Military operational medicine research is grouped into four portfolios of injury prevention and reduction, psychological health and resilience, physiological health, and environmental health and protection. Injury prevention and reduction is validating blast and auditory injury models to deliver guidelines for medical injury criteria, validating medical criteria standards for low level, repetitive blast exposures during breaching (process used to force open closed or locked doors), and verifying performance and musculoskeletal health metrics of Service members in military training environments. Psychological health is determining the effectiveness of behavioral interventions to treat alcohol and substance abuse, evaluating cognitive behavioral interventions (a type of therapy that focuses on examining the relationships among thoughts, feelings and behaviors) for the treatment of PTSD, improving interventions to build resiliency in military families and Warfighters, and improving accuracy of suicide prevention screening. Physiological health is evaluating interventions to promote and sustain weight loss in Warfighters and military families, and validating a policy for vitamin supplementation to reduce injuries during operational and training scenarios. Environmental health and performance is validating decision aids for managing thermal physiological work strain (ability to perform work tasks safely in hot environments), determining health outcomes of chemical exposures (e.g., permethrin, an insecticide used to treat uniforms), determining specific biomarkers of pulmonary health (pertaining to the lungs) from exposures to toxic substances in the deployed environment and specific stress response biomarkers of mild and moderate dehydration for assessing hydration status of Warfighters. Combat casualty care is grouped into portfolios for hemorrhage and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, joint enroute care, and military medical photonics. Hemorrhage and resuscitation is conducting clinical assessments of new agents that control severe internal bleeding and can be administered by first responders at or near the point of injury, developing multiple new TBI diagnostic approaches that when used together provide a more comprehensive diagnosis than what is currently available, evaluate ability to control the immune inflammatory response in hemorrhage.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Neurotrauma is pursuing successful efforts from FY14 in developing biomarkers (substance, such as a protein, indicating the presence of a condition) for TBI, validating results of a clinical trial on Eye-Trac technology to diagnose and assess TBI, and finalizing neuroassessment protocols to standardize treatment practice. Traumatic tissue injury is continuing work on cellular and extracorporeal therapies for acute lung injury and fracture putty for improved bone fracture repairs. In addition the portfolio is developing strategies for maxillofacial (mouth, jaw, and neck) stabilization techniques for initial wound coverage and potential treatments and conducting studies to understand the impact of both the injuries and certain treatments on long term outcomes. Forward surgical intensive critical care is supporting development of a virtual intensive care unit linking patient movement and medical support providers at all levels within the theater of operations, developing guidelines for resuscitative interventions, including comprehensive resuscitation and rewarming of casualties after severe blood loss, continuing a FY14 clinical study using an endovascular (minimally invasive surgery to access regions of the body via major blood vessels) balloon to open occlusions (blocked blood vessels) of the aorta in severe pelvic fracture and hemorrhagic shock cases, and conducting a pilot clinical study of bioengineered blood vessels for vascular trauma. Joint enroute care is continuing the evaluation of the joint-force aeromedical air transport litter immobilization and stabilization platform, with emphasis on patient safety, impact of transport, and medical technology. Military medical photonics is developing technologies that focus on the use of advanced optical technologies, including lasers, spectroscopy, and imaging. Clinical and rehabilitative medicine is continuing efforts and down-selecting products for advanced development for neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Neuromusculoskeletal injury rehabilitation is evaluating the safety and effectiveness of candidate technologies for restoration and rehabilitation medical products. Pain management is tracking methadone and opioid related adverse events; developing novel treatments to control pain, to include battlefield pain, burn pain, neuropathic (nervous system) pain, and chronic pain after amputation; studying modulation of inflammatory cells as an approach to mitigate spinal cord injury neuropathic pain; studying effects of peripherally administered opioids, and developing nerve blocks for knee and hip arthroplasty (joint replacement) in Veterans. Regenerative medicine is focusing on novel approaches to engineer regeneration and repair of damaged muscle tissue, to repair nerve gap injuries, to repair blood vascular injury, and evaluating methods to prevent tissue rejection of allografts (a tissue graft from a donor). Sensory systems is conducting research to verify central auditory processing disorders in blast-exposed Warfighters, evaluating computerized oculomotor vision screening to expedite the diagnosis of TBI-related oculomotor dysfunctions in a military population, testing cochlear implants for active-duty Service members, clinically assessing pharmacotherapy of hidden noise injury toward a molecular understanding of noise-induced hearing loss, developing a portable mild TBI screening device based on evaluation of a patient's gait, preventing noise damage to cochlear synapses, and developing a silica-collagen composite for corneal replacement. ***FY 2016 Plans:***			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Medical simulation and information sciences research will focus on the medical simulation and training portfolio. Medical simulation will complete the virtual tissue advancement research which should provide open source resources to enable developers to create more appropriate virtual tissue simulations. En route training research will continue addressing several issues with providing care to wounded Service members during transport and transfer between providers. Research evaluating the effectiveness of gaming in virtual environments with combat medics will be investigated. Will evaluate training metrics that can best be translated into optimal patient outcomes. This will provide educators the building blocks to create better trainers in the future and begin the long process of linking evidenced-based training to actual patient outcomes. Military infectious diseases research will support a clinical trial to develop therapies for antibiotic-resistant bacteria. Positive results in this clinical trial will be used to support further clinical testing. Skin and soft tissue infections in military trainees will be studied under wound infection prevention and management. The information gained will be used to develop prevention and treatment solutions that will protect the military training force from Staphylococcal skin infection. Progression from FY15 diagnostic assays for selected bacteria that are commonly found in wound infections will be developed for use on an already FDA-approved diagnostic system. These assays will result in quicker diagnosis and appropriate treatment. Military operational medicine research is grouped into four portfolios of injury prevention and reduction, psychological health and resilience, physiological health, and environmental health and protection. Injury prevention and reduction will develop low level blast exposure guidelines and auditory injury standards for health hazard assessments, and will develop predictive models of military performance and the likelihood of musculoskeletal (muscle and bone tissues) injury in military training and applicable to operational environments. Psychological health will incorporate behavioral intervention regimens into clinical practice guidelines for the treatment of alcohol and substance abuse, will compare cognitive behavioral interventions(a type of therapy that focuses on examining the relationships among thoughts, feelings and behaviors)for the treatment of PTSD to current standards of care, and will deliver validated interventions for enhanced resiliency in military families and Warfighters, as well as, more accurate suicide prevention screening tools. Physiological health will develop dietary supplement interventions to promote resiliency to brain injuries and sustain cognitive performance in Warfighters, and will transition policy and guidelines to the Services for improved nutrition during training and operations that will sustain Warfighter performance, health and readiness. Environmental health will incorporate decision aids for managing thermal physiological work strain into physiological health status monitoring for Warfighters to provide extended health, performance and safety assessments, will develop strategies to mitigate adverse health and disease outcomes of chemical exposures (e.g., permethrin, an insecticide used to treat uniforms), and will validate the appropriate stress response biomarkers of pulmonary health (pertaining to the lungs) from exposures to toxic substances in the deployed environment and specific stress response biomarkers of mild and moderate dehydration for assessing hydration status of Warfighters.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Combat casualty care research is grouped into portfolios for hemorrhage and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, joint enroute care, and military medical photonics. Hemorrhage and resuscitation will test immune system modulating drugs to treat hemorrhagic shock, and evaluate drugs to control the immune inflammatory response in hemorrhage. Neurotrauma 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. Traumatic tissue injury will continue the development of a putty to repair fractures, address treatments for acute lung injury, enhance limb and craniofacial salvage, and improve wound healing in the acute setting. Forward surgical intensive critical care will transition to advanced development the vascular occlusion (blocked blood vessels) devices for the treatment of acute hemorrhage and technology to detect cardiovascular collapse. Joint enroute care research will develop new patient immobilization technology, and study the physiologic impact of patient transport. Military medical photonics will develop technologies that focus on the use of advanced optical technologies, including lasers, spectroscopy, and imaging. Clinical and rehabilitative medicine will transfer current efforts and down-select products to advanced development for neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Clinical and rehabilitative medicine will support development of preclinical and pilot/early-phase clinical evaluations of candidate technologies for restoration and rehabilitation strategies and medical products. Specific focus areas will include: neuromusculoskeletal injury rehabilitation strategies and devices; prosthetics; (artificial device that replaces a missing body part); 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); novel therapeutics and devices for pain management; regenerative medicine-based approaches 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; genitourinary (genital and urinary organs) restoration; and 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).			
Accomplishments/Planned Programs Subtotals	168.541	113.048	116.775

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

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 promising products into advanced development.

E. Performance Metrics

Research is evaluated through In-Progress Reviews, quarterly and annual status reports, and Program Office and/or progress reviews to ensure that milestones are being met and deliverables will be transitioned on schedule. The benchmark performance metric for transition of research conducted with medical technology development funding will be 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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 378A / *CoE-Breast Cancer Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
378A: *CoE-Breast Cancer Center of Excellence (Army)*	13.077	11.965	8.664	7.299	-	7.299	5.709	4.068	3.553	3.624	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 2014	FY 2015	FY 2016
Title: Breast Cancer Center of Excellence	11.965	8.664	7.299

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

FY 2014 Accomplishments:

In FY14, the Breast Cancer CoE (Army), also referred to as the Clinical Breast Care Project (CBCP), at Walter Reed National Military Medical Center (WRNMMC) Bethesda continued to accrue subjects annually to the core CBCP protocols. The CBCP continued to acquire, through consented protocol, specimens (normal and abnormal breast tissues and tumors, lymph nodes, metastatic (spread of a cancer from one organ or part to another non-adjacent organ or part) deposits, blood and its components, bone marrow) annually from subjects with all types of breast diseases and cancer. The repository continued to be utilized as the basis for all molecular analyses in CBCP labs, as outlined in the CBCP Core Protocols allowing for global expression analysis of the DNA, RNA, and protein features and as the basis for intramural and extramural collaborations for secondary usage research. CBCP performed whole-genome DNA sequencing on DNA from 60 cases of breast cancer; continued the 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 research activities in CBCP; utilized Clinical Laboratory Workflow System as the data analysis tool and integrated Armed Forces Health Longitudinal Technology Application (AHLTA) data from the military's main electronic medical record; identified research subjects at high-risk for development of breast cancer, and employed risk reduction strategies; completed genomic and proteomic analysis of samples collected at various developmental stages of breast cancer; and presented findings in peer-reviewed publications and at national meetings.

FY 2015 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 378A / *CoE-Breast Cancer Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
The Clinical Breast Care Project will continue performing whole genome DNA sequencing on DNA from cases of breast cancer; continue 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; continue development of an analytical system for integrative data analysis and mining, and further refine a breast knowledge base to support clinical and research activities in the Breast Cancer CoE; utilize 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; identify and counsel patients at high risk for development of breast cancer, and employ risk reduction strategies; perform 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 will present findings in peer-reviewed publications and at national meetings. ***FY 2016 Plans:*** The Clinical Breast Care Project will conduct clinical studies to relate genomic and functional heterogeneity and metastasis with breast cancer patient outcomes. The program will continue 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; conduct studies to determine if there is a correlation between environmental chemical burden and molecular aberrations with breast cancer patient outcomes; conduct human epidermal growth factor receptor 2 (HER2) targeted therapy optimization studies to gain a better understanding of the molecular changes associated with alterations in HER2 expression. Results are expected to lead to a more precise diagnosis and customized treatment plans of patients diagnosed with HER2+ breast cancer.			
Accomplishments/Planned Programs Subtotals	11.965	8.664	7.299

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 379A / *CoE-Gynecological Cancer Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	11.425	10.707	7.570	6.377	-	6.377	4.989	3.555	3.105	3.167	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Gynecologic Cancer Center of Excellence (Army)	10.707	7.570	6.377

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

FY 2014 Accomplishments:

The Gynecologic Cancer Center of Excellence conducted retrospective longitudinal (observations over long periods of historical time) and prospective (observations during a current or future study period) validation studies of biomarker candidates from our previous studies of gynecologic cancer metastasis and recurrence, patient survival, drug resistance and racial disparities in cancer outcome. These investigations rely on collected specimens as well as external biospecimen (materials taken from the human body, such as blood, plasma, urine, etc., that can be used for diagnosis and analysis) collections, such as the Gynecologic Oncology Group (GOG)-249 randomized treatment trial and the Prostate, Lung, Ovarian and Colorectal (PLCO) trial. The candidates identified in our preclinical models are being evaluated in human trials as surrogates/predictors of response to progesterone/progestin and vitamin D. Hypotheses generated from systems-level integration of molecular studies were evaluated using models of ovarian and endometrial (pertaining to the lining of the uterus) cancer. These novel hypotheses establish the framework for the next generation of molecularly targeted therapeutics and diagnostic therapy for gynecologic cancer patient management. Novel molecular candidates are being incorporated into a newly established ensemble of safety and efficacy gynecologic cancer clinical trials aimed at directing endometrial or ovarian cancer patients with specific molecular defects/alterations to tailored molecular targeting regimens, and testing new therapeutics for treatment of newly diagnosed and recurrence/refractory (resistant, unresponsive to surgery or therapy) cancer patients. The intervention trial will remain open

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 379A / *CoE-Gynecological Cancer Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
to accrual to evaluate the effects of stress intervention on recurrence of disease in ovarian cancer, and to evaluate biomarker changes in serial biofluids (biological fluids like blood, urine, breast milk, and cerebrospinal fluid). ***FY 2015 Plans:*** The Gynecologic Cancer Center of Excellence conducts retrospective longitudinal and prospective validation studies of biomarker candidates from our previous studies of gynecologic cancer metastasis and recurrence, patient survival, drug resistance and racial disparities in cancer outcome. These investigations will rely on collected specimens as well as external biospecimen (materials taken from the human body such as blood, plasma, urine, etc that can be used for diagnosis and analysis) collections, such as the Gynecologic Oncology Group (GOG)-249 randomized treatment trial and the Prostate, Lung, Ovarian and Colorectal (PLCO) trial. The candidates identified in preclinical models will be evaluated in human trials as surrogates/predictors of response to progesterone/progestin and vitamin D. Hypotheses generated from systems-level integration of molecular studies will be evaluated using models of ovarian and endometrial cancer. These novel hypotheses establish the framework for the next generation of molecularly targeted therapeutics and diagnostic therapy for gynecologic cancer patient management. Novel molecular candidates will be incorporated into a newly established ensemble of safety and efficacy gynecologic cancer clinical trials aimed at directing endometrial or ovarian cancer patients with specific molecular defects/alterations to tailored molecular targeting regimens, and testing new therapeutics for treatment of newly diagnosed and recurrence/refractory (resistant, unresponsive to surgery or therapy) cancer patients. The intervention trial will remain open to accrual to evaluate the effects of stress intervention on recurrence of disease in ovarian cancer, and to evaluate biomarker changes in serial biofluids. ***FY 2016 Plans:*** The Gynecologic Cancer Center of Excellence will continue validation efforts of identified molecular targets for the treatment of ovarian and endometrial cancers, evaluate the effect of stress intervention on the recurrence of ovarian cancer, work 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, and develop strategies to overcome Taxol(a chemotherapy drug)-resistance in gynecologic cancer cells.			
Accomplishments/Planned Programs Subtotals	10.707	7.570	6.377

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 379A / *CoE-Gynecological Cancer Center of Excellence (Army)*

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 381A / *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	4.822	3.674	3.594	3.520	-	3.520	3.368	3.214	3.057	3.118	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the 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 2014	FY 2015	FY 2016
Title: Cardiac Health Center of Excellence (Army)	3.674	3.594	3.520
Description: The focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by incorporating biomolecular research to detect CVD at an early stage, and identifying markers of increased risk for heart attack in Service members.			
FY 2014 Accomplishments: The Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), continued research studies initiated in FY12-13. Data collection from approved FY12-13 protocols is continuing and being analyzed and synthesized. ICHP is translating and communicating best practices to the services in order to augment clinical practice. Utilizing our Knowledge to Action framework, ICHP are incorporating findings from studies for new hypothesis generation and development of new protocols for FY14-18 to expand the use of point-of-care technology in the ICHP model, whole genome sequencing for early CVD detection, and investigating the use of serum biomarker maps for personalized CVD risk assessment in Wounded Warriors.			
FY 2015 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 381A / *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
The Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), continues conducting research studies initiated in FY13-14. Data collection from approved FY13-14 protocols is analyzed and synthesized. ICHP continues translating and communicating best practices to the services in order to augment clinical practice. Utilizing our Knowledge to Action framework, ICHP continues incorporating findings from our studies for new hypothesis generation and development of new protocols for FY15-19 to expand the use of point-of-care technology in the ICHP model, whole-genome sequencing for early CVD detection, and investigating the use of serum biomarker maps for personalized CVD risk assessment in Wounded Warriors. ***FY 2016 Plans:*** The Cardiac Health Center of Excellence (Army) will develop clinical practice guidelines or tools for cardiovascular health and internal medicine, conduct clinical studies to investigate the effectiveness of lifestyle change interventions and the effects on preclinical atherosclerosis (plaque deposits in artery) measures, continue molecular studies to understand the cardiovascular risk in wounded warriors, explore predictive biomarkers (biological indicators of disease) over time, conduct clinical study to examine effectiveness of point-of-care technology in pre-diabetic patients at risk for cardiovascular disease, and explore predictive patterns for the development of diabetes, a cardiovascular disease equivalent.			
Accomplishments/Planned Programs Subtotals	3.674	3.594	3.520

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 382A / *CoE-Pain Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
382A: *CoE-Pain Center of Excellence (Army)*	3.652	2.784	-	-	-	-	-	-	-	-	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 2014	FY 2015	FY 2016
Title: Pain Center of Excellence (Army)	2.784	-	-
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 2014 Accomplishments: The Pain Center of Excellence members of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) continues to validate major lines of effort including the Defense and Veterans Pain Rating Scale (DVPRS), Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcome Measurement Information System (PASTOR/PROMIS), and Extension for Community Healthcare Outcomes (ECHO) programs. DVCIPM continues to explore pain management therapeutic options to develop and optimize best practice guidelines for the treatment of pain. The research program focuses on evaluation of current medications for improved pain management, clinical assimilation study of integrative medicine modalities including yoga and acupuncture, and exploration of the pathophysiology (study of functional changes associated with disease or injury) and molecular mechanisms of pain with established and new academic partners. DVCIPM continues to provide subject matter expertise, coordination, and guidance to all services and Veterans Health Administration regarding pain-related issues in support of the Pain Task Force.			
FY 2015 Plans: No funding programmed. Program transferred to USUHS starting in FY 2015.			
FY 2016 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 382A / *CoE-Pain Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	2.784	-	-

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 382B / *CoE-Pain Center of Excellence (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
382B: *CoE-Pain Center of Excellence (USUHS)*	-	-	2.722	2.823	-	2.823	2.871	3.247	3.310	3.376	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 2014	FY 2015	FY 2016
Title: Pain Center of Excellence (USUHS)	-	2.722	2.823

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 2014 Accomplishments:
No funding programmed.

FY 2015 Plans:
The Uniformed Services University of the Health Sciences (USUHS) will assume the research oversight of the DVCIPM beginning in FY 2015. The Pain Center of Excellence members of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) will focus primarily on further developing the Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcome Measurement Information System (PASTOR/PROMIS); to include data collection, report generation, and the study of biomarkers in pain. DVCIPM will continue to explore pain management therapeutic options to develop and optimize best practice guidelines for the treatment of pain. The research program will focus on evaluation of current medications for improved pain management, clinical assimilation study of integrative medicine modalities such as battlefield acupuncture, and the exploration of the pathophysiology (functional change) and molecular mechanisms of pain with established, and new academic partners. DVCIPM will provide subject matter expertise, coordination, and guidance to all the armed services and the Veterans Health Administration regarding pain-related issues in support of the Pain Task Force.

FY 2016 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 382B / *CoE-Pain Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
The Uniformed Services University of the Health Sciences (USUHS) will assume the research oversight of the DVCIPM beginning in FY 2015. The Pain Center of Excellence members of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) will focus primarily on further developing the Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcome Measurement Information System (PASTOR/PROMIS); to include data collection, report generation, and the study of biomarkers in pain. DVCIPM will continue to explore pain management therapeutic options to develop and optimize best practice guidelines for the treatment of pain. The research program will focus on evaluation of current medications for improved pain management, clinical assimilation study of integrative medicine modalities such as battlefield acupuncture, and the exploration of the pathophysiology (functional change) and molecular mechanisms of pain with established, and new academic partners. DVCIPM will provide subject matter expertise, coordination, and guidance to all the armed services and the Veterans Health Administration regarding pain-related issues in support of the Pain Task Force.			
Accomplishments/Planned Programs Subtotals	-	2.722	2.823

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	13.516	7.771	6.907	6.260	-	6.260	5.456	4.628	3.300	3.366	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USUHS), the Prostate Cancer Center of Excellence (CoE), formerly a Congressional Special Interest program, the Center for Prostate Disease Research (CPDR), was chartered in 1992 to conduct basic, clinical and translational research programs to combat diseases of the prostate. The CPDR studies prostate cancer and prostate diseases in the military health care 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 22 yrs as recognized by nearly 400 scientific publications. CPDR has also been committed to the research training of the next generation of DoD doctors and scientists (USU medical and graduate students and Walter Reed 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 2014	FY 2015	FY 2016
Title: CoE-Prostate Cancer Center of Excellence (USUHS)	7.771	6.907	6.260
Description: The CPDR is at the forefront of cutting-edge clinical research improving diagnosis and treatment of prostate cancer involving new modalities such as, MRI guided biopsy, and evaluation of new drugs and vaccines for advanced prostate cancer. The CPDR Database continues to highlight emerging issues in prostate cancer management such as, treatment outcomes, ethnic differences and quality of life. In light of current treatment challenges with early detected prostate cancers in PSA testing era and poorly understood biology of prostate cancer, CPDR's high-impact research is focusing on cancer causing genes that will lead to better diagnostic and prognostic markers in the management of the disease. New gene discoveries are also unraveling ethnic differences of prostate cancer biology that has potential to enhance personalized medicine.			
FY 2014 Accomplishments: • Evaluate the efficacy of the newly developed MRI guided biopsy technology in the diagnosis of clinically significant prostate cancer. • Assess new FDA approved drugs and vaccines for the treatment of the metastatic disease. • Investigate minimally invasive modalities for the treatment of early detected prostate cancer. • Analyze the features of onset and progression of prostate cancer among DoD prostate disease patients in relation to ethnicity and obesity. • Complete a new collaborative study with Genomic Health towards the evaluation of early prognostic gene expression markers for differentiating indolent versus aggressive disease.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
• Using the CPDR ERG-MAb, continue to enhance the ERG-based stratification of prostate cancer world-wide in collaboration with Biocare Medical Inc. • Complete the evaluation of ERG oncoprotein frequency in patient populations of China, Germany, Hungary, Japan, India, Malaysia, Philippines and Switzerland. • Develop and enhance strategies to inhibit ERG-mediated oncogenesis using small molecule inhibitors, ERG-MAb and ERG vaccine. • Complete the integrated comparative evaluations of genomics and transcriptomics (expression level of RNA molecules in a given cell population) datasets of African American and Caucasian American patients. • Accelerate prostate cancer-related genome queries by acquiring high-throughput technologies to support advanced bioinformatics capabilities. • Provide solution for the unmet need of prognostic biomarkers that will differentiate between indolent and aggressive disease. Evaluate the NanoString platform towards this goal. • Enhance the CPDR discovery of male hormone signaling-based stratification of prostate cancer, conceptually similar to breast cancer. • Define new mechanisms of male hormone receptor regulation towards developing innovative therapeutic strategies. • Improve non-invasive approaches for the detection of prostate cancer in urine or blood specimens by evaluating prostate cancer antigens, as well as auto-antibodies. • Continue to enhance and transform Prostate Cancer COE database and biospecimen banks to a national center for academic and industrial collaborations to accelerate translational research			
FY 2015 Plans: • Continue to conduct long-term comparisons of efficacy, morbidity, mortality and quality-of-life impact for accepted and emerging treatments for prostate cancer to include robot assisted radical prostatectomy, external beam radiotherapy, brachytherapy, high intensity focused ultrasound, and active surveillance. Assess the impact of these treatments with or without neoadjuvant and adjuvant hormonal or other novel therapies. • Compare the features of disease onset and progression between DoD and civilian prostate cancer patient populations. • Continue focus on long-term studies of the epidemiology to include clinical progression of the disease defined by metastasis, ethnicity, obesity, quality-of-life-adjusted survival and prostate cancer specific death. • Evaluate traditional and emerging molecular marker panels for differentiating indolent versus aggressive disease for guiding treatment decisions. • Leverage the CPDR discovery of the ETS-related gene (ERG), the first major prostate cancer-causing gene identified, which is present in over half of prostate cancers in Western countries, and can be used for precision diagnosis and therapy. • Develop new molecular strategies for improving prostate cancer diagnosis and prognosis, specifically to find replacement for PSA test.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
• Establish the molecular bases of ethnic differences in prostate cancer biology by employing integrated comparative genomics and transcriptomics. • Develop new paradigms for the identification and treatment of highly aggressive prostate cancers based on hormone signaling defects. • Continue to evaluate cancer biology of prostate cancer relevant genes and/or proteins using transgenic and knockout mice models. • Identify molecular determinants of prostate cancer susceptibility in high-risk groups such as African Americans. • Continue to develop and maintain long-term molecular specimen resources for translational investigations at CPDR and collaborations with other institutions. • Maintain the state-of-the-art CPDR translational research infrastructure and expertise to train the next generation of DoD physicians and scientists.			
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. •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.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
•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. •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.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
•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.			
Accomplishments/Planned Programs Subtotals	7.771	6.907	6.260

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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 398A / *CoE-Neuroscience Center of Excellence (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
398A: *CoE-Neuroscience Center of Excellence (USUHS)*	1.822	1.857	-	-	-	-	-	-	-	-	-	-

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 2014	FY 2015	FY 2016
Title: CoE-Neuroscience Center of Excellence (USUHS)	1.857	-	-

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 2014 Accomplishments:

The MCNCoE will complete restructuring of its vision and mission. This restructuring began in 2013 and continues into 2014, and includes re-codifying of the governance of MCNCoE, establishing a permanent external scientific advisory board (SAB). The MCNCoE will fund new clinical research projects through a call for proposals reviewed by SAB, and enhance the capability of MCNCoE to involve clinical neuroscientists across the DoD and at affiliated civilian academic centers in collaborative work with MCNCoE. Plans include involvement of national and international research leaders in the field of neurology from national capital area as well as across military healthcare system. Mission will also refocus on promoting education and training of military medical students, residents, fellows and staff in clinical neuroscience standards of care, outcome measures, and research initiatives with a focus on military-specific neurological conditions. With three ACGME accredited joint (tri-service) Military Neurology training programs in the DoD affiliated with USUHS Neurology, restructuring will include evaluating and augmenting clinical residency research opportunities in neurological disorders seen in military beneficiaries to include co-occurring conditions of special interest such as traumatic brain injury, neurodegenerative conditions, post-traumatic headaches, depression, chronic pain, epilepsy, nerve injury, post-traumatic stress disorders, and other clinical conditions that impact on full recovery. In sync with the President's call for Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, MCNCoE is poised

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 398A / *CoE-Neuroscience Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
to leverage military neuroscience clinicians at USUHS, in the national capital area, across the DoD Military Treatment Facilities, and with MTF academic affiliates to augment the understanding of human brain function which the President has established as an “enormous mystery waiting to be unlocked” (April 2013). ***FY 2015 Plans:*** None, MCNCoE research has been merged into the CNRM beginning in FY 2015. ***FY 2016 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	1.857	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance of individual PIs will be judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the amount of extramural funding received. Performance of the overall program will be also measured on the effective achievement of better communication and research collaborations between neurology researchers across the DOD system, and on the ability of the Program to affect improvements to the academic curriculum at USUHS.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 429A / *Hard Body Armor Testing (Army)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
429A: *Hard Body Armor Testing (Army)*	1.356	-	-	-	-	-	-	-	-	-	-	-

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 2014	FY 2015	FY 2016
Title: Hard Body Armor ***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 2014 Accomplishments:*** No funding programmed. ***FY 2015 Plans:*** No funding programmed. ***FY 2016 Plans:*** No funding programmed.	-	-	-
Accomplishments/Planned Programs Subtotals	-	-	-

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 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 431A / *Underbody Blast Testing (Army)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
431A: *Underbody Blast Testing (Army)*	20.929	10.938	4.818	2.679	-	2.679	1.869	-	-	-	-	-

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 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 Soldier 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 2014	FY 2015	FY 2016
Title: Underbody Blast Testing	10.938	4.818	2.679
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 2014 Accomplishments: The Underbody Blast Testing project focused on generating and providing medical research data needed to support the development of the WIAMan anthropomorphic (resembling a human) test device concept and the first generation prototype. The emphasis was on non-injurious testing conditions and biofidelity data but also included injurious testing. All body regions were addressed including whole-body testing and also prioritized testing of the following body regions, foot and ankle, leg, pelvis, lumbar spine, thoracic spine, cervical spine, torso, head and neck. Validation studies were conducted to contrast injuries observed in theater with those created in the testing program to prioritize research. Emerging medical research data was used to support the protection technology development and the modeling and simulation initiatives.			
FY 2015 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 431A / *Underbody Blast Testing (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
The Underbody Blast Testing project is continuing medical research in the areas initiated in FY14 but with the emphasis shifting during the year from non-injurious conditions to those which cause injuries. This will enable the development of initial human injury probability curves that account for influences unique to the military and to the underbody blast environment. All data are transitioning into the WIAMan project to enable the fabrication of the first and second generation prototype anthropometric test devices (ATDs; manikins or crash test dummies). Validation studies are contrasting injuries observed in theater with those created in the testing program to prioritize further research. Emerging medical research data are supporting the protection technology development and the modeling and simulation initiatives. ***FY 2016 Plans:*** The Underbody Blast Testing project will continue medical research in the areas initiated in FY15 but with the emphasis shifting to perform matched pair testing of the first generation WIAMan prototype. This will enable 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 will inform the development of whole-body injury criteria and the protective technology for use in the underbody blast environment.			
Accomplishments/Planned Programs Subtotals	10.938	4.818	2.679

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 biofidelty response corridors (BRCs), human injury probability curves (HIPC), and injury assessment reference curves (IARCs). Principal investigators (PI's) 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 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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 448A / *Military HIV Research Program (Army)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
448A: *Military HIV Research Program (Army)*	-	6.663	5.773	6.589	-	6.589	6.702	7.579	7.722	7.877	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 2014	FY 2015	FY 2016
Title: Military HIV Research Program	6.663	5.773	6.589
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 2014 Accomplishments: The Military HIV Research Program conducted safety and effectiveness studies with a combination vaccine in human volunteers at clinical trial sites world-wide and down-selected best candidates. Clinical trial results informed the need for further testing in human volunteers to study the ability of HIV vaccine candidates to provoke an immune response that can protect against HIV.			
FY 2015 Plans: Conducting 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. Preparing for large scale production of vaccine candidates from various world-wide subtypes. These candidates will be used in future large scale clinical studies.			
FY 2016 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 448A / *Military HIV Research Program (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
The Military HIV Research Program will complete large scale production and characterization of selected vaccine candidates. Will 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.			
Accomplishments/Planned Programs Subtotals	6.663	5.773	6.589

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) conducted by USAMRMC Decision Gate process to include Defense Health Agency representation.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 830A / *Deployed Warfighter Protection (Army)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
830A: *Deployed Warfighter Protection (Army)*	9.001	5.225	4.553	5.306	-	5.306	5.397	6.105	6.221	6.345	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 carry disease 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Deployed Warfighter Protection	5.225	4.553	5.306
Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects.			
FY 2014 Accomplishments: The Deployed Warfighter Protection (DWFP) research project focused on three major areas to develop products to control biting insects, primarily mosquitoes and sand flies, that transmit force degrading diseases: personal protection systems, new insecticides, and vector control/insecticide application technologies. The personal protection system for today's warfighter relies upon permethrin treated uniforms, applying topical repellents to all exposed skin daily, and sleeping under an insecticide treated net. These countermeasures are often ineffective for several reasons including low user acceptance and the logistical burden of supplying and carrying these products. New personal protection system tools – such as lower concentration repellent chemicals and spatial repellents - were in development by DWFP scientists and their partners. In the area of new insecticides, expanded regulatory requirements and development of insecticide resistance have resulted in a reduction in the number of public health pesticides available for controlling mosquitoes and sand flies. DWFP transitioned a patented Attractive Targeted Sugar Bait (ATSB) delivery technology to a commercial partner as a novel reduced risk pesticide. This new mosquito control product promises to revolutionize mosquito control. To improve the effectiveness and the sustainability of insect control operations in deployed settings, the DWFP focused on developing updated insect control methods, lighter weight insecticide sprayers, and new application technologies that take advantage of engineering advances such as smartphones and robotics.			
FY 2015 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 830A / *Deployed Warfighter Protection (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
The Deployed Warfighter Protection (DWFP) research project is developing products that will enable deployed forces to better protect themselves and control biting insects, primarily mosquitoes and sand flies, which transmit force degrading diseases. The DWFP is focusing 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 is evaluating the feasibility of bite-proof fabrics, studying the durability of factory permethrin-treated uniforms, and searching for a replacement insecticide that safely outperforms the current treated uniforms. Regarding spatial repellents, the DWFP down-selected and is extensively evaluating 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. The DWFP is conducting early field tests of prototype micro-dispensers and textile-based area/spatial-repellent dispensers; and conducting 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, the DWFP is 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 is collaborating with multiple industry partners to develop such new insecticides for EPA registration. For vector control technologies, the DWFP is targeting pesticide delivery methods that are more effective, efficient, and sustainable in austere and tropical environments. In addition to materiel solutions/products, DWFP priorities include knowledge products that support vector control and disease risk reduction to include improving current practices used in the field. ***FY 2016 Plans:*** In FY16 the Deployed Warfighter Protection (DWFP) research project will develop and field tools that enable deployed forces to better protect themselves and control 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. The DWFP will maintain its focus within personal protection systems, new insecticides, and vector control/insecticide application technologies. For enhanced personal protection systems, protective clothing efforts will review pending positive results of the FY15 evaluations of prototype bite proof fabric for commercialization; the alternative to permethrin for treating combat uniforms will complete efficacy evaluations 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 will expand field tests focused on the best performing area/spatial-repellent dispensers evaluated in FY15 and will work with the EPA and associated industry partner to pursue EPA registration for military use. For new insecticides, the DWFP will down select top performing novel molecular pesticides-tested in FY15 for expanded field testing; will conduct faster, more efficient, lab based screening of potential plant-derived and synthetic insecticides to identify promising candidate compounds; and will execute field evaluations of insecticides identified in FY15. For vector control/insecticide application			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
technologies, lab and field testing of insecticide sprayer products identified as promising tools in FY15 will be conducted. Best performing products/sprayers and technologies tested in FY15 will transition to commercial partners for submission to the AFPMB for addition to the National Stock System.			
Accomplishments/Planned Programs Subtotals	5.225	4.553	5.306

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.