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

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

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

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

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development: This program element (PE) provides funding for promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of Department of Defense and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research & Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include medical simulation and information sciences (JPC-1), military infectious diseases (JPC-2), military operational medicine (JPC-5), combat casualty care (JPC-6), radiation health effects (JPC-7), and clinical and rehabilitative medicine (JPC-8). As research efforts mature, the most promising will transition to advanced concept development funding, PE 0604110. For knowledge products, successful findings will transition into clinical practice guidelines.

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

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

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

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

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

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

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

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

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

Medicine. Operational medicine is focused on in garrison care – our next most critical issue post OIF/OEF – and how to care for the whole patient and consideration of comorbidities in treatment of wounded warriors and dependents.

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

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

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

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

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

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

Change Summary Explanation

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

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

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

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

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

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

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

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

N/A

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

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

A. Mission Description and Budget Item Justification

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

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

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

FY 2016 Accomplishments:

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

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

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

C. Other Program Funding Summary ($ in Millions)

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

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Enroute Care R&D - Clinical Translational Focus (AF)	0.997	2.045	2.240
Description: This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on seriously injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into transitionable products. The sub-project areas include: Physiological Effects of Aeromedical Evacuation on patients and crew which includes the optimization of provider performance and patient care, impact of transport times on En-Route Trauma and Resuscitative Care, and En-Route Patient Safety which includes technology advances and assessment. Because patients experience multiple handoffs between teams of caregivers during transport between austere environments and definitive care, efforts in the En-Route Patient Safety sub-project area examine human factors considerations in order to develop new and enhance existing methods to mitigate risk in all En-Route care environments.			
FY 2016 Accomplishments: Analyze final results of swine study investigating post AE effects on coagulation and inflammation, which will lead to a knowledge platform to develop guidelines for evacuation strategies during transport of combat casualties. Pursuant system build and demonstration of the closed loop ventilation and oxygen delivery system, the data from the pre-hospital use of capnometry and the ventilator registry will be used to define the requirements of a system to perform closed loop ventilation. Continue pursuing the AFMS strategic goal A1 to “Transform the En-route Care System” based on war fighter identified gaps and validated requirements. Begin and/or continue work that will improve mission effectiveness in the A2AD environment such as closed loop technologies and enabling capabilities leading to autonomous patient transport.			

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

FY 2016 Accomplishments:

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

FY 2017 Plans:

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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

D. Acquisition Strategy

N/A

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Elimination of Malaria in Southeast Asia (CARB) (Navy)	2.060	2.064	1.548
Description: This project seeks to demonstrate that malaria can be eliminated in a specific geographically defined area of endemicity through a comprehensive multi-disciplined approach including enhanced surveillance, operations research to maximize the impact of intervention strategies, and quality improvement of current tools for malaria elimination. The demonstration will focus on Vietnam where multi-drug resistant malaria is prevalent and as such represents a significant threat to US personnel. Additionally the Vietnamese military and Ministry of Health have a high level of interest in malaria control and will collaborate in the malaria elimination demonstration project significantly improving the chances of success of this project.			
FY 2016 Accomplishments: Enhanced surveillance activities with the Ministry of Health were continued at sites in central Vietnam and on the Laos border. This project has identified risk factors among forest goers, similar to US military personnel in terms of age, health and activity, associated with acquiring malaria. Preliminary data from 2015 and 2016 presented at the American Society of Tropical Medicine and Hygiene (Nov 2016); this information will inform future studies on malaria interventions. To continue work in Vietnam with the Ministry of Health a 2-year work plan was approved in July 2016. Continued recruitment of Vietnam-Australia-US military collaborative study to characterize drug resistance in central Vietnam. Preliminary data, indicating no drug resistance present at study site, presented at the USPACOM Asia Pacific Military Health Exchange in Kuantan, Malaysia (Aug 2016). Cross sectional study protocol approved by Vietnam Ministry of Defense; this project will start in Q1 FY17 targeting people served by military clinics in Gai Lia Province, a remote area on the Cambodia border.			

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

FY 2016 Accomplishments:

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

FY 2016 Accomplishments:

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

FY 2017 Plans:

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

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

FY 2016 Accomplishments:

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

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

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

FY 2016 Accomplishments:

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Expeditionary Medicine Research & Development (Air Force)	1.180	1.160	1.560
Description: This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions. ***FY 2016 Accomplishments:*** Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, cryopreserved blood products, rhabdomyolysis and ischemia-reperfusion injury. Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Begin studies to test and compare point of care testing devices for field use. Continue identification of biomarkers and development of decision support algorithms which predict the need for life saving interventions. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Investigate lifesaving hemorrhage control product that can be introduced to the field of combat casualty care as lifesaving interventions. Determine the efficacy of advanced hemorrhage control technologies including X-Stat and small bore X-Stat			

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

FY 2016 Accomplishments:

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

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

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

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

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

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

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

C. Other Program Funding Summary ($ in Millions)

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

Remarks

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

D. Acquisition Strategy

N/A

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: GDF – Medical Technology Development	113.011	139.454	126.790
Description: Funds provide for the development of medical technology candidate solutions and components of early prototype systems for test and evaluation. Promising drug and vaccine candidates, knowledge products, and medical devices and technologies are selected for initial safety and effectiveness testing in small scale human clinical trials.			
FY 2016 Accomplishments: Medical simulation and information sciences technology maturation completed the virtual tissue advancement research, which provided open source resources to enable developers to create more appropriate physics-based virtual tissue models for simulators. En Route training research identified gaps and technical issues to define requirements for a Joint Evacuation Training Simulation System. Investigators researched knowledge oriented medical training metrics that can best translate into real patient care / outcomes and to begin the process of linking evidence-based training to patient outcomes. Medical simulation explored advanced adaptive tutors that incorporate adult learning cognitive thinking and neuroplasticity models. Continued research to identify predictive markers to differentiate good and poor medical providers. Advancements were made in augmented reality (AR) technologies by evaluating AR applications for the purpose of pre-intervention rehearsal. A joint Service upper & lower airway trainer prototype was transitioned to the advanced developer. Medical simulation research was conducted on the current and			

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

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

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

FY 2016 Accomplishments:
No funding programmed.

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

FY 2016 Accomplishments:

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

Note

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Gynecological Cancer Center of Excellence	0.000	8.655	7.943
Description: The Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecological disease.			
FY 2016 Accomplishments: No Funding Programmed.			
FY 2017 Plans: The FY 2017 program will build on the foundational elements of investigating gynecological carcinogenesis (the initiation, progression, and metastatic spread of cancer) and drug resistance, developing and deploying clinical biomarkers and assays, and improving clinical care and outcome through evaluations of novel therapeutics, prevention strategies, assessments and interventions in gynecological oncology using pre-clinical studies and clinical trials. These efforts are motivated by bench to bedside translation and clinical application emphasizing early detection, molecular profiling and integrated systems level analysis of gynecological malignancies that will have a major impact on diagnosis, treatment efficacy as well as assessment of prognosis,			

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Pain Center of Excellence (USUHS)	2.610	2.641	2.822
Description: The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and its impact on rehabilitation and recovery.			
FY 2016 Accomplishments: The DVCIPM made significant progress toward the 5-year plan for FY15-19 that focuses on further developing the Pain Assessment Screening Tool and Outcomes Registry (PASTOR); complementary and integrative pain management (CIPM) through clinical assimilation studies of modalities and interventional technologies for improved pain management. DVCIPM also had many accomplishments as the MHS's coordinating organization for pain education and clinical policy development. Progress this year includes approval of two protocols: Study 1: "Characterization of Postoperative Pain in Total Knee and Hip Arthroplasty and Assessment of the Defense and Veterans Pain Rating Scale for Persistent Post-Surgical Pain"; and Study 2: "Characterizing the Biopsychosocial Impact on Caregivers in Patients Undergoing Joint Replacement and Cervical/Lumbar Spine Surgery: A Pilot Study". We also expect to complete the DVPRS Pilot Introduction at 3 MHS Medical Treatment Facilities; analysis of "Characterization of Postoperative Pain in Total Knee and Hip Arthroplasty and Assessment of the Defense and Veterans Pain Rating Scale for Persistent Post-surgical Pain"; facilitate the MHS Opioid Safety Strategy; Federal Medicine Mandatory Prescribing Training; MHS Pain Campaign; and finalize MOU's with States of West Virginia, Virginia and Duke University. Additionally, we are working with USU CNRM about building/housing DVCIPM Biobank and establishing a scientific/ programmatic oversight board.			
FY 2017 Plans:			

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
FY 2016 Accomplishments: Precision Medicine Research Focus: • Streamlined the first MRI-ultrasound fusion image guided biopsy technology in a DoD medical center (at WRNMMC, Bethesda) in enhancing detection of clinically significant prostate cancers. • To address the urgent need in forecasting outcomes for patients with early-detected prostate cancer, CPDR completed the second validation of a biopsy-based, 17-gene panel prognostic assay (Oncotype DX® Prostate Cancer Test). In the racially diverse cohort of DoD patients, this test demonstrated similar performance in predicting adverse pathology and cancer progression (Genomic Health Inc. /USU-HJF CRADA; Cullen et al., European Urol, 2015; Brand et al., Urology, 2016). • To overcome limitations of currently used serum PSA test and to improve diagnostic assays, CPDR has completed the first multi-omics study (proteome, lipidome and metabolome) using 700 serum specimens from CPDR biospecimen bank. A twelve analyte diagnostic panel has been identified and is now under further validation (Berg Pharma/ USU-HJF CRADA, U.S. Patent Application, 2016). • Toward improving the prostate cancer treatment decision-making process, a new study was completed examining factors that influence decision-making among DoD patients who participated in the CPDR WRNMMC multidisciplinary clinic (Hurwitz et al., Urol Oncol, 2016). • A prospective quality of life (QoL) outcomes study was completed that examined patients choosing active surveillance compared to those biopsied but not diagnosed with prostate cancer to better understand the impact of cancer diagnosis and factors that might improve QoL in such patients (Pham et al., J Urol, 2016). Health Disparity Research: • First insights into the prostate cancer genomes were developed establishing significant differences of the two main prostate cancer driver genes (ERG and PTEN) between African American and Caucasian men and new discoveries highlighting genes (LSAMP, CHD1) enriched in African American prostate cancers (Petrovics et al., EBioMedicine 2015, and CRADA with Harvard Medical School). These findings led to the development of ethnicity-informed biomarker panels towards enhancing the diagnosis and prognosis of prostate cancer (two U.S. Patent Applications 2016). • Completed a meta-analysis of world-wide assessment of the most common prostate cancer driver gene ERG, revealing striking differences in ERG frequencies between races and geographic regions (Sedarsky et al Nature Reviews Urology 2016). • Completed a definitive study of ERG oncoprotein (nearly 1,000 patients, including the largest cohort of African American patients) highlighting novel prognostic features of ERG-based stratification of prostate cancer (Cullen et al., European Urology Focus, 2016). • A recently completed study of BRCA1 and BRCA2 germline mutations provided new insights into the higher frequency of BRCA2 mutations in African American patients and overall association with aggressive prostate cancer (Petrovics et al., American Urologic Association (AUA) Annual Meeting, 2016, selected for AUA highlights and press release within the top 3% of presentations of 2,800 at AUA 2016).			

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

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

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

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

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

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

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

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

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

Note

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

A. Mission Description and Budget Item Justification

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

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

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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

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

A. Mission Description and Budget Item Justification

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
insecticide sprayer products identified as promising tools in FY 2015 was conducted with a focus on remotely operated and/or autonomous spraying capabilities. Best performing products/sprayers and technologies tested in FY 2015 transitioned to industry partners for commercialization and submission to the AFPMB for addition to the National Stock System. ***FY 2017 Plans:*** In FY 2017, the DWFP research program is leading translational research to develop and field tools that protect against emerging infectious disease threats and enable deployed forces to better protect themselves from biting insects, primarily mosquitoes, which transmit force degrading diseases. This is accomplished through research, testing and evaluation of products, patent submissions, licensing, and EPA registrations for new insecticides and bite protection tools. The DWFP continues to maintain its focus on three priority areas: personal protection systems, new insecticides, and vector control/insecticide application technologies. For enhanced personal protection systems, protective clothing technology (bite proof fabric) is patented and transitioning to the U.S. Army Natick Soldier Research, Development and Engineering Center for advanced development; pending results of efficacy testing and EPA registration of the alternative to permethrin for treating combat uniforms, technology is transitioning to the Services for incorporation into future combat uniforms. Within this same focus area under area/spatial repellents, FY 2016 results and EPA registration of transfluthrin is driving commercialization strategies and licensing agreements to field a novel area/spatial-repellent device to provide passive protection from biting mosquitoes. In the insecticides development portfolio, the exploration of natural/biopesticides with improved environmental and human safety profiles continue. Molecular pesticide development and testing partnerships with two major global insecticide developers continues. Field evaluation of first generation, species-specific molecular insecticides targeting mosquitoes is starting; following completion of the AFPMB led Vector Control Capabilities Gap Analysis, the AFPMB pesticides committee has identifed priority insecticide gaps, which drive FY 2017 funding for pesticides-related R&D. For vector control/insecticide application technologies, a new silent backpack sprayer developed by the DWFP program, licensed by industry in FY 2015 and improved by the commercial partner in FY 2016 is becoming commercially available. The program is exploring new technologies to enable remotely operated and/or autonomous insecticide application. Partners are adding data to two vector control mobile apps which serve as decision support tools for deployed entomologists. Technologies developed provide solutions to prevent malaria needed by the President's Malaria Initiative and partners in the WHO Global Malaria Program. ***FY 2018 Plans:*** In FY 2018, the DWFP research program will continue to lead translational research to develop and field tools that protect against emerging infectious disease threats and enhance protection of deployed forces from biting insects, primarily mosquitoes, which transmit force degrading disease pathogens. The program will also enhance coordination with MIDRP and GEIS programs to strengthen complementary research and surveillance outputs. The completion of the AFPMB Vector Control Capabilities Gap Analysis in FY 2016 will be used to continue acquisition-based research and development requirements in a Capability Needs			

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

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

E. Performance Metrics

To be determined.

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

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

A. Mission Description and Budget Item Justification

DoD Cancer Moonshot Program - DoD Framingham

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

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

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance Metrics to be determined.

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

C. Other Program Funding Summary ($ in Millions)

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

Remarks

D. Acquisition Strategy

Acquisition Strategy is to be determined.

E. Performance Metrics

Performance metrics to be determined.