Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115DHA *I Medical Technology Development*							
COST ($ in Millions)	**Prior Years**	**FY 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	2,480.064	1,177.334	1,272.109	220.916	-	220.916	212.794	234.117	240.572	243.942	Continuing	Continuing
300A: *CSI - Congressional Special Interests*	1,864.085	975.057	1,041.539	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
238C: *Enroute Care Research & Development (Budgeted) (AF)*	8.351	3.282	1.340	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
238D: *Core Enroute Care R&D - Clinical Translational Focus (AF)*	0.000	0.000	0.997	2.045	-	2.045	2.240	2.282	2.328	2.375	Continuing	Continuing
238E: *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.000	0.997	2.045	-	2.045	2.239	2.282	2.327	2.374	Continuing	Continuing
243A: *Medical Development (Lab Support) (Navy)*	97.042	31.378	37.580	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
247A: *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	0.200	0.000	2.060	2.064	-	2.064	1.548	0.000	0.000	0.000	Continuing	Continuing
247B: *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	0.425	0.000	1.040	1.135	-	1.135	1.238	0.000	0.000	0.000	Continuing	Continuing
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	6.340	2.205	1.700	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
284C: *Core Human Performance R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.003	2.349	-	2.349	2.664	2.762	2.817	2.873	Continuing	Continuing
284D: *Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)*	0.000	0.000	1.002	2.348	-	2.348	2.663	2.761	2.816	2.872	Continuing	Continuing
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	14.997	1.917	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency										Date: February 2016		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115DHA *I Medical Technology Development*							
285B: *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	0.000	0.000	0.929	1.147	-	1.147	1.350	1.360	1.387	1.415	Continuing	Continuing
285C: *Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	0.000	0.928	1.147	-	1.147	1.349	1.360	1.387	1.415	Continuing	Continuing
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	29.236	10.792	8.173	7.725	-	7.725	5.034	9.230	11.169	11.392	Continuing	Continuing
307C: *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.000	1.500	-	1.500	2.235	2.375	2.463	2.512	Continuing	Continuing
307D: *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.000	1.000	1.500	-	1.500	2.235	2.375	2.463	2.512	Continuing	Continuing
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	7.616	4.544	1.180	1.160	-	1.160	1.560	1.640	1.673	1.706	Continuing	Continuing
308C: *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.503	1.500	-	1.500	1.497	1.501	1.531	1.562	Continuing	Continuing
308D: *Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	0.000	1.502	1.499	-	1.499	1.497	1.500	1.530	1.561	Continuing	Continuing
309A: *Regenerative Medicine (USUHS)*	13.908	8.388	9.489	7.323	-	7.323	7.373	8.327	10.209	10.413	Continuing	Continuing
373A: *GDF - Medical Technology Development*	296.680	99.064	116.294	139.454	-	139.454	134.790	147.378	147.764	149.276	Continuing	Continuing
378A: *CoE-Breast Cancer Center of Excellence (Army)*	25.042	7.907	7.299	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency										Date: February 2016		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115DHA *I Medical Technology Development*							
378B: *CoE-Breast Cancer Center of Excellence (USU)*	0.000	0.000	0.000	9.900	-	9.900	9.088	10.280	10.475	10.685	Continuing	Continuing
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	22.132	6.909	6.377	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
379B: *CoE-Gynecological Cancer Center of Excellence (USU)*	0.000	0.000	0.000	8.655	-	8.655	7.943	8.987	9.158	9.341	Continuing	Continuing
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	8.496	3.281	3.520	3.051	-	3.051	2.697	2.914	3.118	3.180	Continuing	Continuing
382A: *CoE-Pain Center of Excellence (Army)*	6.436	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
382B: *CoE-Pain Center of Excellence (USUHS)*	0.000	2.484	2.823	2.641	-	2.641	2.822	3.310	3.376	3.445	Continuing	Continuing
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	21.287	6.303	6.260	7.900	-	7.900	7.250	8.203	8.359	8.526	Continuing	Continuing
398A: *CoE-Neuroscience Center of Excellence (USUHS)*	3.679	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
429A: *Hard Body Armor Testing (Army)*	1.356	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
431A: *Underbody Blast Testing (Army)*	31.867	4.397	2.679	1.869	-	1.869	0.000	0.000	0.000	0.000	-	-
448A: *Military HIV Research Program (Army)*	6.663	5.270	6.589	6.070	-	6.070	6.359	7.360	7.877	8.035	Continuing	Continuing
830A: *Deployed Warfighter Protection (Army)*	14.226	4.156	5.306	4.889	-	4.889	5.123	5.930	6.345	6.472	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development: This program element (PE) provides funding for promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of DoD and multi-agency priority investments in science, technology, research,

and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research & Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include medical simulation and information sciences (JPC-1), military infectious diseases (JPC-2), military operational medicine (JPC-5), combat casualty care (JPC-6), radiation health effects (JPC-7), and clinical and rehabilitative medicine (JPC-8). As research efforts mature, the most promising will transition to advanced concept development funding, PE 0604110. For knowledge products, successful findings will transition into clinical practice guidelines.

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

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

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

For the Army Medical Command, three Centers of Excellence (CoE) receive medical technology development funds. The Breast Cancer CoE (Army) provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. The Gynecological Cancer CoE (Army) focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and biologic therapeutics (a medicinal preparation created by a biological process used to treat diseases) for the management of gynecological disease. Management of the Breast and Gynecological Cancer CoEs will transfer from the Army to the Uniformed Services University beginning in FY 2017. The Cardiac Health CoE (Army) provides evidence-based personalized patient engagement approaches for comprehensive cardiac event prevention through education, outcomes research and technology tools, as well as molecular research to detect cardiovascular disease at an early stage to ultimately discover a signature for cardiovascular health, to find new genes that significantly increase risk for heart attack in Service members and other beneficiaries, and identify molecular markers of obesity and weight loss.

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

In FY 2015, Congressional Special Interest (CSI) funds were added to support peer-reviewed research programs: Amyotrophic Lateral Sclerosis (ALS), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis, Cancer, Lung Cancer, Orthopedics, Spinal Cord, Vision, Traumatic Brain Injury and Psychological Health (TBI/PH), Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer's, Reconstructive Transplant, Tuberous Sclerosis Complex, Duchenne Muscular Dystrophy, and Epilepsy. CSI funds were also provided for Joint Warfighter Medical Research, Orthotics and Prosthetics Outcomes, HIV/AIDS Program Increase, Global HIV/AIDS Prevention, and Restore Core Research Funding Reduction. Because of the CSI annual structure, out-year funding is not programmed.

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

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

For the Uniformed Services University of the Health Sciences (USUHS), medical development programs include the Prostate Cancer Center of Excellence (CoE), the Center for Neuroscience and Regenerative Medicine (CNRM), the Pain CoE, the Breast Cancer CoE, and the Gynecological Cancer CoE. The Prostate CoE, formerly a CSI, was chartered in 1992 to conduct basic, clinical, and translational research programs to combat diseases of the prostate. The Center's mission is fulfilled primarily through its three principal programs -- the Clinical Translational Research Center, the Basic Science Research Program, and the Tri-Service Multicenter Prostate Cancer Database, which encompasses its clinical research work with other participating military medical centers. These affiliated sites contribute data and biospecimens

obtained from prostate cancer patients who participate in clinical trials. CNRM brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to TBI research. CNRM research programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center. Beginning in FY17, the Breast Cancer CoE funding line and the Gynecological Cancer CoE funding line are transferred from the Army to USUHS.

B. Program Change Summary ($ in Millions)	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	226.131	231.051	250.488	-	250.488
Current President's Budget	1,177.334	1,272.109	220.916	-	220.916
Total Adjustments	951.203	1,041.058	-29.572	-	-29.572
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	970.934	1,041.539			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-19.731	-			
• Federally Funded Research and Development Center (FFRDC) Reduction	-	-0.481	-	-	-
• Realignment of the Medical Development Laboratory Support Program	-	-	-38.211	-	-38.211
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-13.599	-	-13.599
• Restore USUHS Breast, GYN, and Prostate Cancer Centers of Excellence	-	-	8.547	-	8.547
• Rebalance Joint Program Committees	-	-	13.691	-	13.691

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

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

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

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

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

Change Summary Explanation

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

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

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

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

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

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

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

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

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
300A: *CSI - Congressional Special Interests*	1,864.085	975.057	1,041.539	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research	7.500	7.500
FY 2015 Accomplishments: This Congressional Special Interest initiative provided funds for research in Amyotrophic Lateral Sclerosis (ALS). ALS is a degenerative neuronal disorder that causes muscle weakness and atrophy throughout the body. The ALS Research Program is a broadly-competed, peer-reviewed research program with the goal to contribute to a cure for ALS by funding innovative preclinical research to develop new treatments for ALS. Two award mechanisms were released in March, 2015 the Therapeutic Development Award and the Therapeutic Idea Award. Applications were received in August 2015 followed by scientific peer review in October 2015. Funding recommendations were made at programmatic review in December 2015. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Amyotrophic Lateral Sclerosis (ALS) Research.		
Congressional Add: 293A - Autism Research	6.000	7.500
FY 2015 Accomplishments: This Congressional Special Interest initiative provided funds for research in Autism Research, to improve treatment outcomes of Autism Spectrum Disorder (ASD), lead to a better understanding of ASD, and integrate basic science and clinical observations by promoting innovative research. The Autism Research Program funds research at universities, hospitals, nonprofit and for-profit institutions. Two award mechanisms were released in April 2015, the Clinical Trial Award and the Idea Development Award. Applications		

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
were received in October 2015 followed by scientific peer review in December 2015. Funding recommendations will be made at programmatic review in February 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Autism Research.		
Congressional Add: 296A - Bone Marrow Failure Disease Research ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative funded research for bone marrow failure diseases. The mission of the program is to sponsor innovative research that will advance the understanding of inherited and acquired bone marrow failure diseases, and improve the health and life of individuals living with these diseases, with the ultimate goal of prevention and/or cure. This effort has solicited research proposals focused on bone marrow failure syndromes and their long-term effects from the basic science and clinical research sectors. In FY 2015, applications were accepted through one funding opportunity, the Idea Development Award, released in March 2015. Applications were received in July 2015 followed by scientific peer review in September 2015. Funding recommendations were made at programmatic review in November 2015. Award(s) will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Bone Marrow Failure Disease Research.	3.200	3.000
Congressional Add: 310A - Peer-Reviewed Ovarian Cancer Research ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative funded research in Ovarian Cancer. In striving to achieve the goal of eliminating ovarian cancer, the Ovarian Cancer Research Program (OCRP) is challenging the research community to address high impact, innovative research. The FY 2015 OCRP supported innovative ideas that provide new paradigms, leverages critical resources, facilitates synergistic, multidisciplinary partnerships, and cultivates the next generation of investigators in ovarian cancer. Five award mechanisms were offered: Pilot Award, Clinical Translational Award, Investigator-Initiated Research Award, Ovarian Cancer Academy Award recruiting Early-Career Investigators, and the Outcomes Consortium Award. Application submission deadlines were in August 2015 and in September 2015 followed by scientific peer reviews in September and October 2015. Funding recommendations were made at the programmatic reviews in December 2015. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Ovarian Cancer Research.	20.000	20.000
Congressional Add: 328A - Multiple Sclerosis Research ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative funded research in Multiple Sclerosis (MS). The mission of the program is to support pioneering concepts and high-impact research relevant to the prevention, etiology (causes or origins of), pathogenesis (the mechanism(s) that cause(s) MS or the	5.000	6.000

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
development of MS), assessment, and treatment of MS. Two award mechanisms were offered: Investigator-Initiated Research Award and Pilot Clinical Trial Award. Applications were received in September 2015 followed by scientific peer review in November 2015. Funding recommendations will be made at programmatic review in January 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Multiple Sclerosis Research.		
Congressional Add: 335A - Peer-Reviewed Cancer Research ***FY 2015 Accomplishments:*** This Congressional Special Interest research initiative was for the study of cancers designated by Congress. The goal of the Peer-Reviewed Cancer Research Program is to improve the quality of life by decreasing the impact of cancer on Service members, their families, and the American public. The funds appropriated by Congress were directed for research in the following areas: colorectal cancer, genetic cancer research, kidney cancer, Listeria vaccine for cancer, liver cancer, melanoma and other skin cancers, mesothelioma (rare form of cancer developed from the protective lining that cover many of the internal organs of the body caused by exposure to asbestos), myeloproliferative disorders (abnormal growth of blood cells in bone marrow), neuroblastoma, pancreatic cancer and stomach cancer. Three award mechanisms to support these topic areas were released in April 2015: the Career Development Award, the Idea Award with Special Focus, and the Translational Team Science Award. One additional funding opportunity, the Horizon Award, was released in July 2015. Applications were received in August and September 2015 followed by scientific peer review in November and December 2015. Funding recommendations will be made at programmatic review in February 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Cancer Research.	50.000	50.000
Congressional Add: 336A - Peer-Reviewed Lung Cancer Research ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative funded research in Lung Cancer. The goal of the Peer-Reviewed Lung Cancer Research Program is to eradicate deaths from lung cancer to better the health and welfare of military Service members, Veterans, their families, and the American public. This research effort offered five award mechanisms in FY 2015: the Career Development, the Clinical Exploration, the Concept, the Expansion and the Idea Development Awards. Applications were received in August and September 2015 followed by scientific peer review in October and November 2015. Funding recommendations will be made at programmatic review in January 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Lung Cancer Research.	10.500	12.000
Congressional Add: 337A - Peer-Reviewed Orthopedic Research	30.000	30.000

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

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
common end result -- degeneration of the critical components of the eye and impairment or loss of vision. The results of this research are intended to be used for restoration and maintenance of visual function to ensure and sustain combat readiness. Basic, translational and clinical research efforts were sought to ensure that results of scientific research will be used to directly benefit the lives of military, Veteran and civilian populations. For FY 2015, the VRP focused on 1) prevention and early diagnostic, intervention and mitigation strategies for specific injuries, 2) advanced deployable devices to diagnose traumatic eye injuries, and 3) epidemiological research of military eye trauma and TBI-related vision dysfunction. To meet the goals of the program, one award mechanism was used to support vision research, the Translational Research Award. A program announcement was released in July 2015, pre-applications were received in September 2015, and applications were received in December 2015. Scientific peer review was conducted in in February 2016 with programmatic review occurring in April 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Vision Research.		
Congressional Add: 352A - Traumatic Brain Injury/Psychological Health Research ***FY 2015 Accomplishments:*** The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest research program aimed to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and combat-related TBI on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, Veterans, family members, caregivers, and communities. Key priorities of the TBI/PH research program supported projects aligned with the National Research Action Plan, addressed Congressional intent, enabled significant research collaborations, and complemented ongoing Department of Defense (DoD) efforts to ensure the health and readiness of our military forces by improving upon and optimizing the standards of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In addition to supporting service-requested nominations, individual Broad Agency Announcement applications, and promising ongoing studies, program announcements were released to solicit applications that address these priorities. The Neurosensory and Rehabilitation Research Award program announcement supported preclinical research and clinical trials addressing TBI within specific focus areas of pain management, hearing loss/dysfunction, balance disorders, tinnitus, vision, or physical rehabilitation associated with TBI. The FY 2015 Comprehensive Universal Prevention Health Promotion Intervention Award program announcement was released in September 2015.Scientific peer and programmatic reviews will follow, and awards for selected applications will be made no later than September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Traumatic Brain Injury/Psychological Health Research.	105.000	97.792
Congressional Add: 380A - Peer-Reviewed Breast Cancer Research	120.000	120.000

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
FY 2015 Accomplishments: This Congressional Special Interest research initiative was for Breast Cancer research. The Breast Cancer Research Program challenged the scientific community to design research that addresses the urgency of ending breast cancer. Applications were required to address at least one of ten overarching challenges, which were focused on preventing breast cancer, identifying what makes the breast susceptible to cancer, determining why some women get breast cancer while others do not, distinguishing aggressive breast cancer from indolent cancers, conquering the problems of over-diagnosis and overtreatment, identifying what drives breast cancer growth and determining how to stop it, identifying why some breast cancers become life-threatening metastases, determining how to prevent recurrence, revolutionizing treatment regiments with safe and effective interventions, and eliminating the mortality associated with metastasis. To support the program's vision of ending breast cancer, five award mechanisms were developed to support meritorious breast cancer research: Breakthrough Award Levels 1 and 2, Breakthrough Award Levels 3 and 4, Distinguished Investigator Award, Era of Hope Scholar Award, and Innovator Award. The Breakthrough Award accepts applications under four funding levels, depending on the scope of the research project, which could range from initial proof-of-concept to clinical trials. Program Announcements were released in March and July 2015. Application submission deadlines were in April, July, November, and December 2015. Scientific peer reviews were held in June and September 2015 and in February 2016. Programmatic reviews were held in August and November 2015 and in January and April 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Breast Cancer Research.		
Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research	80.000	80.000
FY 2015 Accomplishments: This Congressional Special Interest research was for Prostate Cancer research. The vision for this effort is to conquer prostate cancer by funding research to eliminate death from prostate cancer and enhance the well-being of men experiencing the impact of the disease. To address the most critical current needs in prostate cancer research and clinical care, the Prostate Cancer Research Program (PCRP) developed four overarching challenges to be addressed by the research community: (1) develop better tools for early detection of clinically relevant disease, (2) distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer, (3) develop effective treatments and address mechanisms of resistance for men with high risk or metastatic prostate cancer, and (4) develop strategies to optimize the physical and mental health of men with prostate cancer. In addition, research projects are being solicited in the areas of biomarker (biological indicator of health outcomes and disease) development, genetics, imaging, mechanisms of resistance, survivorship and palliative care, therapy, and tumor and microenvironment biology. To meet these goals for FY 2015, the following seven award mechanisms were developed: Collaborative Undergraduate HBCU Student Summer Training Award, Exceptional Responders Award, Health Disparity Research Award, Idea		

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

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

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

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

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
FY 2015 Accomplishments: This Congressional Special Interest research initiative complemented the funding for the HIV/AIDS research program. Several potential vaccine candidates were down-selected for further testing in human volunteers to study their ability to provoke an immune response that can protect against HIV either as a single vaccine or combination of various subtypes. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for HIV/AIDS Program.		
Congressional Add: 459A - Peer-Reviewed Epilepsy Research ***FY 2015 Accomplishments:*** This Congressional Special Interest research initiative was for Peer-Reviewed Epilepsy Research. This was a new program in 2015. The program will support studies to examine the interconnection between traumatic brain injury and epilepsy. Longitudinal epidemiological research, including epilepsy surveillance will be studied within the context of improving patient care. Mechanistic research to examine how brain injury produces epilepsy and potential preventative avenues will be encouraged as focus areas for research. The Idea Development Award Program Announcement were released in July 2015, with pre-applications and applications were received in August and November 2015. Scientific peer review will be held in February 2015 with programmatic review occurring in April 2016. Awards will be made no later than September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Epilepsy Research.	7.500	7.500
Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported technology development efforts in medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, and clinical and rehabilitative medicine (Project 373A). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported technology development efforts in medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, and clinical and rehabilitative medicine (Project 373A).	94.584	138.509
Congressional Add: 474A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported research for the Breast Cancer CoE	7.575	1.457

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
(Project 378A), Gynecological Cancer CoE (379A), Cardiac Health CoE (381A), Underbody Blast Testing (431A), Military HIV Research (448A) And Deployed Warfighter Protection (830A). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supports research for the Cardiac Health CoE (381A), Military HIV Research (448A) and Deployed Warfighter Protection (830A).		
Congressional Add: 474B – Program Increase: Restore Core Research Funding Reduction (Navy) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported Navy research efforts to Combat Antibiotic Resistant Bacteria (Projects 247A,B) and Medical Development Laboratory Support (Project 243A). ***FY 2016 Plans:*** No Funding Programmed.	6.856	0.000
Congressional Add: 474C – Program Increase: Restore Core Research Funding Reduction (Air Force) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported Air Force research in Enroute Care (Project 238C), Human Performance (284B), Operational Medicine (285A), Force Health Protection (307B), and Expeditionary Medicine (308B). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported Air Force research in Force Health Protection (307B).	10.228	2.928
Congressional Add: 474D – Program Increase: Restore Core Research Funding Reduction (USUHS) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported University research in Regenerative Medicine (Project 309A), Prostate Cancer CoE (383A) and Pain CoE (382B). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0603115. Funds supported University research in Regenerative Medicine (Project 309A), Prostate Cancer CoE (383A), Breast Cancer CoE (378B), Gynecological CoE (379B) and Pain CoE (382B).	2.514	2.553
Congressional Add: 495 - Peer-Reviewed Tick-Borne Disease Research ***FY 2015 Accomplishments:*** N/A ***FY 2016 Plans:*** This Congressional Special Interest was new in FY 2016. The initiative was directed to address research studying under-funded or gap areas of tick borne disease and will incorporate military priorities and	0.000	5.000

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
relevance where applicable. Award mechanisms will be offered through Program Announcements, followed by scientific peer review and programmatic review of submitted proposals. Funding recommendations and awards will be made by September 2017.		
Congressional Add: 496 -Trauma Clinical Research Program ***FY 2015 Accomplishments:*** N/A ***FY 2016 Plans:*** This Congressional Special Interest (CSI) was new in FY 2016 and was directed to advance trauma research. The DoD is creating a coordinated, multi-institution, clinical research network of civilian and military trauma centers to address the military relevant priorities and gaps in trauma care. The Combat Casualty Care Research Program of the US Army Medical Research and Materiel Command will include this CSI funding with core DHP RDTE program funding for future planning and execution of a Request for Proposals and future award for a Trauma Clinical Research Network.	0.000	10.000
Congressional Add: 540A - Global HIV/AIDS Prevention (Navy) ***FY 2015 Accomplishments:*** This Congressional Special Interest project supports Global HIV/AIDS Prevention research. Program emphasis is placed on (1) building a national research infrastructure by funding large, multidisciplinary program projects focused on detection; (2) encouraging innovative approaches to research by funding new ideas and technology with or without supporting preliminary data; and (3) recruiting new, independent investigators for careers in research, as well as more senior investigators new to the research field. The strategy for the FY 2015 Congressional directed research identified above is to stimulate innovative research through a competitive, peer reviewed research program, as well as focused medical research at intramural and extramural research sites. Specific research efforts include HIV/AIDS. The HIV/AIDS Prevention program conducts on-site visits to determine eligible areas for technical assistance and resource support. The program provides support to defense forces in the following areas: (1) HIV prevention, which includes training of medical personnel and peer educators, education of military members, provision of condoms and other prevention materials, provision of educational materials such as brochures, posters, and booklets (2) care for HIV-infected individuals and their families to include provision of electronic medical record programs, medications to treat HIV-related issues, physician education, and clinic infrastructure support, (3) treatment services including provision of laboratory services such as HIV test kits, and other laboratory equipment, and (4) Strategic Information including systems to collect information on the effectiveness of HIV treatment and prevention programs and generate databases of such information to guide treatment and prevention programs.	8.000	8.000

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
The HIV/AIDS Prevention Program provided technical assistance and resource support for 22 foreign defense forces in FY 2015. Accomplishments include over 59,000 individuals that received testing and counseling services for HIV; over 80 testing facilities (laboratories) supported with the capacity to perform clinical lab tests; 99,155 military members and their dependents targeted with HIV prevention interventions; more than 180 health care workers successfully completing an in-service training program; and support of 12,195 pregnant women with HIV testing and counseling services. ***FY 2016 Plans:*** This Congressional Special Interest project supports Global HIV/AIDS Prevention research. Program emphasis is placed on (1) building a national research infrastructure by funding large, multidisciplinary program projects focused on detection; (2) encouraging innovative approaches to research by funding new ideas and technology with or without supporting preliminary data; and (3) recruiting new, independent investigators for careers in research, as well as more senior investigators new to the research field. The strategy for the FY 2015 Congressionally directed research identified above is to stimulate innovative research through a competitive, peer reviewed research program, as well as focused medical research at intramural and extramural research sites. Specific research efforts include HIV/AIDS. The HIV/AIDS Prevention program conducts on-site visits to determine eligible areas for technical assistance and resource support. The program provides support to defense forces in the following areas: (1) HIV prevention, which includes training of medical personnel and peer educators, education of military members, provision of condoms and other prevention materials, provision of educational materials such as brochures, posters, and booklets (2) care for HIV-infected individuals and their families to include provision of electronic medical record programs, medications to treat HIV-related issues, physician education, and clinic infrastructure support, (3) treatment services including provision of laboratory services such as HIV test kits, and other laboratory equipment, and (4) Strategic Information including systems to collect information on the effectiveness of HIV treatment and prevention programs and generate databases of such information to guide treatment and prevention programs. Annual program data collection is currently being conducted and accomplishments for FY 2015 will be reported after the collection is complete. Because of the CSI annual structure, out-year funding is not programmed.		
Congressional Add: 660A - Tuberous Sclerosis Complex (TSC)	6.000	6.000
FY 2015 Accomplishments: The Congressional Special Interest research initiative for Tuberous Sclerosis Complex (TSC) encouraged innovative research to improve the lives of individuals with TSC through understanding the pathogenesis and manifestations of TSC and developing improved diagnostic and treatment approaches. Within this context, the FY 2015 TSC research program encouraged applications that address vital		

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
program focus areas for mechanisms underlying clinical manifestations and/or novel therapeutic strategies. This research effort offered three award mechanisms to support TSC research: Idea Development, Exploration-Hypothesis Development, and Pilot Clinical Trial Awards. Applications were received in July 2015, followed by scientific peer review conducted in September 2015, and funding recommendations were made at programmatic review in December 2015. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Tuberous Sclerosis Complex (TSC) Research.		
Congressional Add: 790A - Duchenne Muscular Dystrophy ***FY 2015 Accomplishments:*** This Congressional Special Interest initiative was for research focused on Duchenne Muscular Dystrophy (DMD) (gene mutations in skeletal muscle proteins affecting approximately 1 in 3,600 boys causing muscle degeneration and eventual death). The goal for this research program is to extend and improve the function, quality of life, and lifespan for all individuals diagnosed with DMD by supporting research to better inform the development of drugs, devices, and other interventions and promote their effective clinical testing. This program encourages applications that address: 1- discovery and qualification of pharmacodynamic (the biochemical and physiological effects of drugs on the body, their mechanisms of action, and the relationship between drug concentration and effect), prognostic, and predictive biomarkers; 2- assessment of clinical trial outcomes; 3- extension or expansion of preclinical translational data; and 4- novel interventions to improve clinical care and quality of life. A total of three award mechanisms were offered in 2015, the Investigator-Initiated Research Award, the Translational Leverage Award and the Therapeutic Idea Award. Applications were received in October 2015 with scientific peer review was conducted in January 2016 and programmatic review will be conducted in March 2016. Awards will be made by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Duchenne Muscular Dystrophy Research.	3.200	3.200
Congressional Adds Subtotals	975.057	1,041.539

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

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

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 238C / *Enroute Care Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
238C: *Enroute Care Research & Development (Budgeted) (AF)*	8.351	3.282	1.340	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Enroute Care Research & Development (Budgeted) (AF)	3.282	1.340	0.000

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

FY 2015 Accomplishments:

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 238C / *Enroute Care Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
to provide input on the transition of research findings into fielded products, clinical guidance, and policies. Transitioned the Comprehensive Adult Extracorporeal Membrane Oxygenation (ECMO) Support Program. ***FY 2016 Plans:*** Evaluate the benefit of cabin altitude restriction, the incidence of gas emboli through the circuit during transport, and the benefit of adding additional venous drainage during periods of hypoxemia. Evaluate current practices regarding transportation of critically ill patients without traumatic injuries and incorporate results in the DoD critical care training curriculum. Retrospectively describe traumatic cardiopulmonary arrest (TCPA) patients in the battlefield and determine if they meet the current published guidelines for resuscitation of traumatic cardiac arrest. Identify independent predictors that are associated with increased survival among TCPA patients in a combat theater. Describe mechanical ventilation methods during the transport of critically injured and ill patients by CCATT to validate existing CCATT clinical practice guidelines. Conduct an Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) Psychiatric Medical Evacuation (MEDEVAC) analysis of psychological assessment, diagnostic categorization, risk and protective factors, aeromedical classification, aeromedical transportation safety and disposition of military personnel aeromedically evacuated from OEF/OIF for psychiatric reasons to facilitate recommendations to improve patient, aircrew and aircraft safety. Develop algorithm based on sensitive and specific markers of renal damage to aid in predicting the efficacy/safety of further volume resuscitation and to predict pre-hospital prognosis in warfighters. Evaluate the combat-feasible Extracorporeal Life Support (ECLS) approach to managing complex injuries which occur in combat such as massive trauma with exsanguination, trauma pneumonectomy, retro-hepatic IVC injuries, and severe traumatic brain injury (sTBI). Record the indications for ECLS initiation and transport across the DoD to implement a robust electronic alert system for identifying critically ill patients in a deployed environment. Continue research to identify the effects of altitude on various injury states and investigate biomarkers as predictors of acute lung injury, acute kidney injury, and traumatic brain injury prior to AE. Begin simulation research program: validate skill / outcome measures, develop simulation improvements / technologies to achieve those outcomes, understand perishability of skills. Continue medical device clinical validation at altitude work. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	3.282	1.340	0.000

C. Other Program Funding Summary ($ in Millions)

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

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 238C / *Enroute Care Research & Development (Budgeted) (AF)*

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 238D / *Core Enroute Care R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
238D: *Core Enroute Care R&D - Clinical Translational Focus (AF)*	0.000	0.000	0.997	2.045	-	2.045	2.240	2.282	2.328	2.375	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Core Enroute Care R&D - Clinical Translational Focus (AF)	0.000	0.997	2.045

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

FY 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
Analyze final results of swine study investigating post AE effects on coagulation and inflammation, which will lead to a knowledge platform to develop guidelines for evacuation strategies during transport of combat casualties. Pursuant system build and demonstration of the closed loop ventilation and oxygen delivery system, the data from the pre-hospital use of capnometry and the ventilator registry will be used to define the requirements of a system to perform closed loop ventilation. Continue pursuing the AFMS strategic goal A1 to “Transform the En-route Care System” based on war fighter identified gaps and validated requirements.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 238D / *Core Enroute Care R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Begin and/or continue work that will improve mission effectiveness in the A2AD environment such as closed loop technologies and enabling capabilities leading to autonomous patient transport. FY16 program cost is $2.25M; UFR = $1.253M ***FY 2017 Plans:*** Continue pursuing the AFMS strategic goal A1 to “Transform the En-Route Care System” based on war fighter identified gaps and validated requirements. Begin and/or continue work that will improve mission effectiveness in the A2AD environment such as closed loop technologies and enabling capabilities leading to autonomous patient transport. Continue to identify independent predictors that are associated with increased survival among patients in a combat theater and update clinical practice and training guidelines to support resulting best practices. Establish database for medical evacuation treatment indicators with care and resolution outcomes.			
Accomplishments/Planned Programs Subtotals	0.000	0.997	2.045

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 238E / *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
238E: *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.000	0.997	2.045	-	2.045	2.239	2.282	2.327	2.374	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)	0.000	0.997	2.045

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

FY 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
Continue development of the En-Route care retrospective research database. Continue research to identify the effects of altitude on various injury states and investigate biomarkers as predictors of acute lung injury, acute kidney injury, and traumatic brain injury prior to AE. Begin simulation research program: validate skill / outcome measures, develop simulation improvements / technologies to achieve those outcomes, understand perishability of skills. Continue medical device clinical validation at altitude work. Continue closed loop medical interventions research and development. Begin to characterize vibration on transport platforms. Begin to investigate medication efficacy at altitude. Continue investigating new research and development requirements

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 238E / *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
based on results of prior studies and warfighter gap analyses. Begin development of an animal-free, human-free tool for testing efficacy and safety of medications and biochemical pain mitigation strategies during aeromedical evacuation flights. ***FY 2017 Plans:*** Investigate operational questions through use of the En-Route care retrospective research database. Continue research to identify the effects of altitude on various injury states and investigate biomarkers as predictors of acute lung injury, acute kidney injury, and traumatic brain injury prior to AE. Continue simulation research program: validate skill / outcome measures, develop simulation improvements / technologies to achieve those outcomes, understand perishability of skills. Continue medical device clinical validation at altitude work. Continue closed loop medical interventions research and development. Continue to characterize vibration on transport platforms. Continue initial investigation of medication efficacy at altitude. Continue investigating new research and development requirements based on results of prior studies and warfighter gap analyses.			
Accomplishments/Planned Programs Subtotals	0.000	0.997	2.045

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 243A / *Medical Development (Lab Support) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
243A: *Medical Development (Lab Support) (Navy)*	97.042	31.378	37.580	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Medical Development (Lab Support) (Navy)	31.378	37.580	0.000

Description: Funding in this project code covers operating and miscellaneous support costs at RDT&E laboratories, including facility, equipment and civilian personnel costs that are not directly chargeable to RDT&E projects. Excluded costs include military manpower and related costs, non-RDT&E base operating costs, and military construction costs, which are included in other appropriate programs.

FY 2015 Accomplishments:

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

FY 2016 Plans:

Continue to provide operating support for eight medical RDT&E labs across 15 product lines to develop products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter, and enable the labs to meet or exceed science performance metric objectives.

FY 2017 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 243A / *Medical Development (Lab Support) (Navy)*

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 247A / *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
247A: *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	0.200	0.000	2.060	2.064	-	2.064	1.548	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Elimination of Malaria in Southeast Asia (CARB) (Navy)	0.000	2.060	2.064
Description: This project seeks to demonstrate that malaria can be eliminated in a specific geographically defined area of endemicity through a comprehensive multi-disciplined approach including enhanced surveillance, operations research to maximize the impact of intervention strategies, and quality improvement of current tools for malaria elimination. The demonstration will focus on Vietnam where multi-drug resistant malaria is prevalent and as such represents a significant threat to US personnel. Additionally the Vietnamese military and Ministry of Health have a high level of interest in malaria control and will collaborate in the malaria elimination demonstration project significantly improving the chances of success of this project.			
FY 2015 Accomplishments: No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative.			
FY 2016 Plans: The first objective of this project, which was to enhance the malaria surveillance in Vietnam, was completed in FY14. The malaria surveillance system was optimized to define exactly where transmission is occurring with novel mapping to support targeted interventions and the monitoring and evaluation of their impact. It built upon existing funded projects, leveraging investments from the US Government, international partners and non-Government Agencies.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 247A / *Elimination of Malaria in Southeast Asia (CARB) (Navy)*

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 247A / *Elimination of Malaria in Southeast Asia (CARB) (Navy)*

D. Acquisition Strategy

N/A

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 247B / *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
247B: *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	0.425	0.000	1.040	1.135	-	1.135	1.238	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)	0.000	1.040	1.135
Description: This project seeks to demonstrate that the impact of sepsis from resistant and other high risk organisms in Egypt can be mitigated through the Austere Environment Consortium for Enhanced Sepsis Outcomes (ACESO) approach of discovering common, host-based pathogenic pathways for improved recognition and management of sepsis. This project will improve understanding of pathogenesis and antimicrobial resistance mechanisms through network and biomarker analysis to offer unique opportunities for improving sepsis diagnosis and management. Most specifically, ACESO will execute biomarker discovery identifying diagnostic and prognostic biomarker panels which may improve sepsis management in all environments including resourced and austere			
FY 2015 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 247B / *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative. ***FY 2016 Plans:*** FY14 efforts were directed towards the development and approval of research protocols by NAMRU-3 and Ministry of Health Scientific Review Board and Institutional Review Board, as well as, the development of agreements, securing required equipment and supplies, and the recruitment of necessary contract staff to initiate patient enrollment during first quarter of FY15. FY15 efforts supported the continuation of the observational study of patients with sepsis in Egypt admitted to the Abbassia Fever Hospital, adjacent to NAMRU-3, Cairo. The goals of this study are to 1) identify diagnostic and prognostic markers, 2) investigate common pathogenic pathways, 3) describe the spectrum of pathogens causing sepsis, 4) describe the treatment strategies currently in use, and 5) assess the long-term sequelae. Adult patients with suspected infection and evidence of systemic inflammation will be considered for enrollment. Laboratory testing will augment the testing routinely performed at the hospital microbiology laboratory, and will include diagnostic tests (e.g. blood cultures, malaria smears, HIV tests, and serology), molecular diagnostics (e.g. microarray analysis, multiplex PCR, and sequencing), and assays measuring the host-response (biomarker assays and host transcriptome arrays). Sophisticated analytic and statistical approaches will be applied to this complex data set to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways. FY16 funding will support the continuation of the observational study at the Abbassia Fever Hospital and the sophisticated analytic and statistical approaches will be applied to this complex data set to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways. ***FY 2017 Plans:*** FY17 funding will support the translation of observational studies at the Abbassia Fever Hospital to develop sophisticated analytical and statistical approaches to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways. Additionally, antimicrobial resistance patterns determined from the observational studies will be combined with the prognostic markers for sepsis and common pathogenic pathway data to achieve improve patient outcomes.			
Accomplishments/Planned Programs Subtotals	0.000	1.040	1.135

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 247B / *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*

D. Acquisition Strategy

N/A

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284B / *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	6.340	2.205	1.700	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)	2.205	1.700	0.000

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

FY 2015 Accomplishments:

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

FY 2016 Plans:

Expand evaluations of promising fatigue and cognitive management modalities. Conclude efforts identifying the effects of combining over-the-counter stimulants with Modafinil, which may stimulate the need for further research. Apply results from high altitude and hypoxia studies to refine this line of research to define what is a “safe” altitude and potentially spur operational changes. Implement plans to pursue human systems integration studies, focusing on identified gaps. Mature a comprehensive program working to define and mitigate the extreme physiological demands of higher altitudes to include decompression sickness and hypoxia. Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284B / *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
magnify each other. Advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention. ***FY 2017 Plans:*** No funding programmed.			
Accomplishments/Planned Programs Subtotals	2.205	1.700	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 284C / *Core Human Performance R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
284C: *Core Human Performance R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.003	2.349	-	2.349	2.664	2.762	2.817	2.873	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Core Human Performance R&D - Clinical Translational Focus (AF)	0.000	1.003	2.349
Description: This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to Operational and Environmental Challenges to Performance.			
FY 2015 Accomplishments: No funding programmed.			
FY 2016 Plans: Introduce early prevention, diagnosis, treatment, and evidence-based training through curriculum modification within U.S. Air Force basic training. Develop clinical and training protocols, in cooperation with military training instructors and clinical treatment teams, to evaluate and improve overall trainee and active duty fitness (e.g., by measuring fitness assessment scores), health and nutrition and augment the capabilities and professional growth of independent duty medical technicians (IDMTs). Evaluate U.S. Air Force basic military trainees with non-fracture lower extremity musculoskeletal injuries for clinical and operational outcomes to determine if gait and activity modification by a certified athletic trainers reduces the risk of progression to lower extremity stress fracture and decreases the discharge rate and days of training lost for lower extremity injuries. Demonstrate exposure to non-hypoxic hypobaria induces subcortical white matter injury by MRI. Evaluate changes in inflammatory serum markers of hyperoxemia/oxidant stress.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284C / *Core Human Performance R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Mature a comprehensive program working to define and mitigate the extreme physiological and physical demands of higher altitudes to include decompression sickness and hypoxia. Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions magnify each other. Advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention. ***FY 2017 Plans:*** Design a comprehensive program to define and evaluate the extreme physiological demands of AETC technical school training students to mitigate fatigue and cognitive overload, reduce injury and improve performance. Advance understanding of appropriate selection pertaining to new accessions, job placement, injury reduction and retention. Examine biomarkers for cognitive and physiological performance. Continue to evaluate model of hypobaria-related white matter damage for detection of the biological/neuropathological indicators. Develop neuroprotection and/or neurotreatment therapies designed to mitigate hyperoxemic brain injury/effects. Integrate high altitude and hypoxia studies to support a mature acceleration and altitude research program focused on defining and mitigating extreme physiological and physical demands of higher altitudes to include decompression sickness and hypoxia. Continue work to determine operator/aircrew needs to optimize performance in high altitude environment to inform operational changes and determine safe altitudes for long-term exposures. Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions magnify each other. Continue to advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention.			
Accomplishments/Planned Programs Subtotals	0.000	1.003	2.349

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284D / *Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
284D: *Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)*	0.000	0.000	1.002	2.348	-	2.348	2.663	2.761	2.816	2.872	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in piloted aircraft, as well as remote piloted aircraft operations, aviation performance and injury prevention, and personalized optimization of performance of AF personnel. The sub-project areas include: AF Aircrew Physiology and Cognition Performance which includes pilot performance monitoring and interventions, fatigue management, AF unique Physiological Performance and Targeted Conditioning Mitigation which includes personalized performance and training techniques for optimal performance, Aviator Injury Prevention and Performance Optimization, Select training and simulation to optimize performance of AF operators and personnel, and identification of solutions related to Operational and Environmental Challenges to Performance.

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

Description: This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in piloted aircraft, as well as remote piloted aircraft operations, aviation performance and injury prevention, and personalized optimization of performance. The sub-project areas include: AF Aircrew Physiology and Cognition Performance which includes pilot performance monitoring and interventions, fatigue management, AF unique Physiological Performance and Targeted Conditioning Mitigation which includes personalized performance and training techniques for optimal performance, Aviator Injury Prevention and Performance Optimization, Select training and simulation to optimize performance of AF operators and personnel, and identification of solutions related to Operational and Environmental Challenges to Performance.

FY 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
Continue assessment of in-flight pilot performance monitoring. Begin assessment of potential physiological measures capable of capturing physiological and cognitive state of AF pilot and operator personnel. Evaluate current/planned technologies employed in current generation aircraft against human performance limitations to address changes needed to technology or identify

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284D / *Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
performance optimization techniques. Conclude efforts identifying the effects of combining over-the-counter stimulants with Modafinil, which may stimulate the need for further research. Apply results from high altitude and hypoxia studies to refine this line of research and potentially spur operational and training changes, and identify areas needed for further research. Implement plans to pursue human systems integration studies, focusing on identified gaps. Conduct operational based vision research. ***FY 2017 Plans:*** Complete capability advancement and finalize in-flight pilot respiratory monitoring system. Continue assessment of physiological measures capable of capturing physiological and cognitive state of AF pilot and operator personnel. Implement findings from the integration of high altitude and hypoxia studies to support and initiate acceleration and altitude research to meet pilot/ aircrew mission needs. Continue operational based vision research with a focus on platform specific critical operational vision performance.			
Accomplishments/Planned Programs Subtotals	0.000	1.002	2.348

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 285A / *Operational Medicine Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	14.997	1.917	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Operational Medicine Research & Development (Air Force)	1.917	0.000	0.000

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

FY 2015 Accomplishments:

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 285A / *Operational Medicine Research & Development (Budgeted) (AF)*

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 285B / *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
285B: *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	0.000	0.000	0.929	1.147	-	1.147	1.350	1.360	1.387	1.415	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Core Operational Medicine R&D - Clinical Translational Focus (AF)	0.000	0.929	1.147

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

FY 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
Optimize physiologic conditions during free composite tissue transfer, ameliorate ischemia/reperfusion injury, and maximize reconstructive reliability. Perform allo-transplantation with donor tissue applied drug eluting microspheres, immunocloaking, and additional donor tissue specific treatments to minimize immunoreactivity and produce successful immunotolerance in a large animal model. Optimization of tissue reliability, minimization of inflammatory response, and eventual induction of immunotolerance will aid in vastly expanding and improving reconstructive outcomes in injured service members as well as restoration of long-term near-normal form and function. Evaluate donor graft targeted immunomodulation in a vascularized composite tissue model to reduce the requirement for systemic immunosuppression in reconstructive transplantation. Evaluate advanced techniques for mitigation of ischemia-reperfusion injuries to improve reliability of composite tissue transfer and provide translatable principles for immediate application to battlefield injuries. Establish the feasibility of systemic reloading of graft-implanted hydrogels to prolong free graft survival with minimal systemic drug exposure by comparing drug levels in Reconstructive Transplantation (RT) tissue components (skin, muscle, or draining lymph nodes) to systemic blood levels using mass spectrophotometry,

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 285B / *Core Operational Medicine R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
clinicopathologic correlation, cellular, antibody, cytokine, proteomic and genomic profiling, and immunomonitoring (cytokine, gene and cellular transcripts). Examine Hypertonic saline (HTS) use following damage control laparotomy (DCL) to decrease the time to primary fascial closure (PFC) and reduce the number of complications associated with an open abdomen. Determine the safety of adding autologous stromal vascular fraction (SVF) cells to a standard fat graft and if the added cryostored SVF cells improve fat graft outcomes in soft tissue to advance new techniques in regenerative medicine that promote repair (by the subject's own body tissues) of the post-treatment defect. Examine the use of sub-dissociative dose ketamine (SDDK) for the treatment of acute exacerbations of chronic pain in an emergency department setting to reduce the amount of opioids required for adequate control of pain and to limit the number of adverse effects associated with treatment. Characterize increasing treatment of warriors on long-term opioids for quality and safety of care to decrease adverse events and reduce unintentional drug overdose deaths. Develop and test the feasibility and impact of a prescription monitoring surveillance and intervention tool for identifying nonmedical use of scheduled opioids. Evaluate the utility of behavioral therapies for opioid addiction to protect against relapse. Determine whether clinically available medications that can reverse effects of typical dissociatives might also reverse the effects of synthetic cannabinoids, providing treatment options for emergency room administration of medications to individuals intoxicated with synthetic cannabinoids and suffering from the resulting acute dissociative effects. Perform longitudinal data analyses to develop a brief self-report screener for use in military training that will identify couples at risk for negative relationship outcomes. Characterize effectiveness measures MiCare implementation on Patient Centered Medical Home (PCMH) to improve evidence-based quality care, ensure appropriate patient utilization/provider productivity, and enhance perception of patient–provider communication and workflow satisfaction. FY16 program cost is $3.929M, UFR = $3.000M ***FY 2017 Plans:*** Further identify practical health delivery platforms using health services research to adapt innovative, evidence-based health solutions to improve troop to beneficiary health. Pilot feasibility studies and expand to large scale, standardized implementation research to address current high diagnoses rates of musculoskeletal pain, anxiety/depressive disorders, autism, obesity and other chronic disease states. Research health priorities using data analytics to define and validate occupational and physical health performance measures to identify degrees of health needed to optimize, sustain and enhance health practices to improve troop reliability. Initiate research to enhance accession health and minimize/prevent training injury patterns. Assess the physical and psychological/cultural impact of Women in Combat. Research and incorporate health information technology to develop clinical communication networks to train providers and engage beneficiaries through integrated communities of care. Utilize patient genomic information to individualize population health services. Continue regenerative/reconstructive research to validate technologies for surgical reconstruction of service members with previously non-reconstructable injuries. Expand composite tissue transfer to replantation of traumatic amputations and to advanced reconstruction with composite tissue allotransplantation. Provide guidance on the clinical impact of the new cell-based therapies as applied to improvements in fat grafting for warfighters requiring			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 285B / *Core Operational Medicine R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
IED and burn wound reconstruction, and beneficiaries with other traumatic injuries. Continue development in the areas of chronic pain following traumatic brain injury, post-traumatic stress disorder, and substance abuse. Implement risk mitigation system to identify non-medical use of opioids in a military setting. Adapt a stepped, couple relationship-skills intervention that fits within a military training context and evaluate its effectiveness at improving future outcomes for military couples. Provide a comprehensive interpretation of PCM team productivity and clinic workflow post-MiCare implementation. FY17 program cost is $3.147, UFR = $2.000M			
Accomplishments/Planned Programs Subtotals	0.000	0.929	1.147

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 285C / *Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
285C: *Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	0.000	0.928	1.147	-	1.147	1.349	1.360	1.387	1.415	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)	0.000	0.928	1.147

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

FY 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
Conduct research into select AF Flight Medicine enrollees identifying health and performance preventative and intervention needs. Evaluate human performance practice on general AF populations identifying success and areas of improvement required. Perform evaluation of aeromedical care service delivery methods assessing for efficacy and efficiency in promoting beneficial outcomes in operators and their families.

FY 2017 Plans:
Further advance understanding of health and performance practice on general AF populations identifying successes and areas of improvement required to mature comprehensive research programs. Continue to evaluate aeromedical care service delivery methods assessing for efficacy and efficiency in promoting beneficial outcomes in operators and their families. Initiate research

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 285C / *Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
program to identify biomarkers of traumatic brain injury in warfighters using minimally invasive sample collection methods to improve aeromedical patient care. Continue development of autonomously designed DNA-based therapeutic interventions against emergent infectious diseases. Explore an integrated operational medicine approach to characterize individual health and provide comprehensive treatment to improve human health and performance.			
Accomplishments/Planned Programs Subtotals	0.000	0.928	1.147

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	29.236	10.792	8.173	7.725	-	7.725	5.034	9.230	11.169	11.392	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force)	10.792	8.173	7.725
Description: This project area seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

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

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

AFMS Innovation initiatives include demonstration of projects to drive, streamline, and empower continuous process improvements and innovations, leading practices, disruptive and transformative innovation into enterprise-wide efforts to enhance an agile culture of innovative through use of an innovations exchange web portal platform. Analyze genomics survey data to identify gaps in genomic education, and development of educational programs to correct these gaps. Utilize patient modeling algorithms to identify pharmacogenomics interventions that can improve patient health and reduce healthcare costs across the AFMS. Provide further analysis in educational interventions for the proper use of genetic testing within the AFMS. Research for pharmacogenomics for anti-depressants and pain medication within the AFMS. Analysis of methodologies and challenges associated with the establishment of an AFMS genome data repository for future implementation of genomic medicine.

FY 2015 Accomplishments:

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
in support of early detection of emerging threats by providing accurate and timely environmental situational awareness. Provided mission-directed, persistent surveillance and real-time hazard identification as key elements to deployable, operational and emerging threat monitoring and event planning for disaster preparedness and response. ***FY 2016 Plans:*** Continue evaluating foreign made, clinical lasers to validate that the devices meet U.S. safety and health standards. Continue the investigation of biomarkers associated with laser lesions, which is exploring the biophysical interactions between directed energy and biological tissue at optical frequencies. Continue developing a retinal injury atlas database for use by clinicians and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Start transition to the AF public health community a recently developed compact, insulated, leak-proof, laboratory-approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory; also, explore technology transfer potential to the civilian public health sector. Continue research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Complete studies to further improve HAPSITE capabilities to detect other classes of chemicals. Complete the Problem Definition Study (PDS) to develop a Portfolio Management Tool to define a research strategy that identifies critical and specific phased research studies and technology developments that are required to detect and characterize airborne pollution hazards in the deployed environment with specific relevance to the AF. Perform field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant emerging exposure hazards; nanomaterials, directed energy weapons, newly detected operational chemicals. Continue genomic studies to include analysis of conditions with operational and clinical importance, based on an assessment of AFMS needs. Develop methodologies that are extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Develop nanoparticle sensing prototype for infectious disease threat identification and surveillance. Develop capabilities for remote sensing. Address the enhancement of health risk assessment capabilities to detect, measure and assess biological, chemical, directed energy and other physical contaminants in the environment during deployments and operations, mitigating the consequences of hazardous health exposures and allowing for the restoration of safe use of essential contaminated resources. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference. Provide an analysis of the Chagas disease threat within high-risk military populations to determine if force health protection measures should be implemented to decrease exposure risk. Transition a compact, deployable tool for blood-oxygen-level dependent MRI with neurofeedback to modulate hyperactivity of the auditory cortex and reduce tinnitus symptoms as the first compact tool that can be used outside of the MR environment. Monitor service			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
members periodically for the efficacy of surgical treatment for their non-battle musculoskeletal injury and analyze trends of injury (e.g., gender- service, and age-specific trends) as well as rates for subsequent surgery whether at the site of the index injury or on the contralateral side. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue CUS enrollment and data analysis as well as development of a digital BioBank prototype. Initiate projects to support transition of nano-biodressing to address wound remediation and healing. Initiate research to examine the pharmacogenomics of anti-depressants and anti-psychotics within framework of the NIH MEDSEQ infrastructure as well as research to identify variants associated with differential response to trauma. Complete three studies on topics that include statin pharmacogenomics, genetic risk testing and coaching, and analysis of epigenetics associated with stress and high altitude. Continue support for the AFMS Clinical Utility Study to include additional enrollment to expand the existing AFMS cohort, analysis of impact of genomic risk data on study participants, investigation of diseases and conditions of operational importance. Continue to mature methodologies and requirements for Air Force Medical System bioinformatics tools and processes, including the development of the AFMS digital Biobank. Increase support for Integrative Medicine efforts to provide advancement of research into complementary and alternative medicine (CAM) programs to identify safe and effective therapies to treat patients. CAM therapies will serve as an adjunct to conventional therapies for a holistic approach to patient management. Continue to expand efforts to identify Advanced Diagnostics to include telemedicine initiatives and other advanced technology solutions; and leveraging of computational biology research. Development of a digital Biobank to be used as a platform for the clinical implementation of genomic medicine with the capability to combine and create genomic data registries for use in research missions which will help collaborators to extract and transfer data in a virtual portal and create a test bed for methodologies and protocols for security, storage and integration of genomic data. Advanced Diagnostics program cost is $2.500M per year; and the Integrative Medicine program is $2.800M per year. Both programs supports the AFMS' strategic goals under Enterprise Management, specifically E3 (Define Requirements and Utilize Emerging Knowledge, Research and Technology) and E6 (Empower Continuous Process Improvement and Innovation). ***FY 2017 Plans:*** Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Start transition to the AF public health community a recently developed compact, insulated, leak-proof, laboratory-approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory; also, explore technology transfer potential to the civilian public health sector. Continue research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Complete studies to further improve HAPSITE capabilities to detect other classes of chemicals. Complete the Problem Definition Study (PDS) to			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
develop a Portfolio Management Tool to define a research strategy that identifies critical and specific phased research studies and technology developments that are required to detect and characterize airborne pollution hazards in the deployed environment with specific relevance to the AF. Perform field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant emerging exposure hazards; nanomaterials, directed energy weapons, newly detected operational chemicals. Begin Development of novel tools for pathogen identification. Develop targeted mitigations for white matter hyperintensity abnormalities. Continue to evaluate leading causes of missed training time and medical attrition from training, significantly affect military readiness, to improve the health and well-being of trainees and active duty service members; save significant money from the associated medical and non-medical costs, including long-term disability costs; and improve operational readiness by eliminating disruptions in the training pipeline. Continue subject enrollment for analysis of the Chagas disease threat within high-risk military populations and implement force protection measures to decrease exposure risk. Advance force health protection in the area of occupational and environmental health by delivering real time detection and identification of airborne biological health hazards at the detector's point of operation and improving capabilities of Air Force Medical Service Preventive Medicine personnel by providing rapid detection and notification of the presence of infectious disease agents. Continue the development of new strategies for prevention, identification, and treatment of injuries caused by emerging biological, chemical, directed energy and other physical threats. Continue to develop rapid, ruggedized, field-forward methodologies to detect health threats, including the ongoing evaluation of nanoparticle sensing prototypes for infectious disease threat identification and surveillance. Identify new molecular targets (plasma markers) for enhanced detection and prevention. Provide further analysis of genetic, epigenetic, proteomic and pharmacogenetic testing to advance force health protection measures within the AFMS. Advanced Diagnostics program cost is $2.500M per year; and the Integrative Medicine program is $2.800M per year. Both programs supports the AFMS' strategic goals under Enterprise Management, specifically E3 (Define Requirements and Utilize Emerging Knowledge, Research and Technology) and E6 (Empower Continuous Process Improvement and Innovation).			
Accomplishments/Planned Programs Subtotals	10.792	8.173	7.725

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
307C: *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.000	1.500	-	1.500	2.235	2.375	2.463	2.512	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Core Force Health Protection R&D - Clinical Translational Focus (AF)	0.000	1.000	1.500
Description: This project seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*

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

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

FY 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
Continue evaluating foreign made, clinical lasers to validate that the devices meet U.S. safety and health standards. Continue the investigation of biomarkers associated with laser lesions, which is exploring the biophysical interactions between directed energy and biological tissue at optical frequencies. Continue developing a retinal injury atlas database for use by clinicians and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Start transition to the AF public health community a recently developed compact, insulated, leak-proof, laboratory-approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory; also, explore technology transfer potential to the civilian public health sector. Continue research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Complete studies to further improve HAPSITE capabilities to detect other classes of chemicals. Complete the Problem Definition Study (PDS) to develop a Portfolio Management Tool to define a research strategy that identifies critical and specific phased research studies and technology developments that are required to detect and characterize airborne pollution hazards in the deployed environment with specific relevance to the AF. Perform field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant nanomaterials. Proposed expansion of Genomic Studies to include analysis of conditions with operational and clinical importance, based on an assessment of AFMS needs. Continue AFMS Innovation initiatives including demonstration projects for process improvements, leadings practices, disruptive and transformative technologies. Analysis of genomics survey data to identify gaps in genomic education, and development of educational programs to correct these gaps. Utilization of patient modeling algorithms to identify pharmacogenomic interventions that can improve patient health and reduce healthcare costs across the AFMS. Provide further analysis in educational interventions for the proper use of genetic testing within the AFMS. Research for pharmacogenomics for anti-depressents and pain medication within the AFMS. Analysis of methodologies and challenges associated with the

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
establishment of an AFMS genome data repository for future implementation of genomic medicine. To augment capabilities for genomic research within the AFMS, the USAF will continue participation in National Human Genome Institute pharmacogenomic research projects. Continue to develop a high-content, rapid throughput toxicological capability with pluripotent cells allowing for a rapid screening of possible threats in the aerospace environment. Develop methodologies that a extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Perform a comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed. Complete evaluating foreign made, clinical lasers to validate that the devices meet U.S. safety and health standards. Complete the investigation of biomarkers associated with laser lesions, which is exploring the biophysical interactions between directed energy and biological tissue at optical frequencies. Continue developing a retinal injury atlas database for use by clinicians and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Complete the transition to the AF public health community a recently developed compact, insulated, leak-proof, laboratory-approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory. Complete the technology transfer to the civilian public health sector. Complete research to develop miniaturized sensors to identify hypoxic/ toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Develop new and innovative technologies to detect and assess hazardous chemical, biological, and physical agents relevant to AF deployment and garrison operations. Initiate studies identified the Problem Definition Study (PDS) and research strategy to detect and characterize airborne pollution hazards (to include burn pits) in the deployed environment. Continue field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant nanomaterials. Continue AFMS Innovation demonstration initiatives, including process improvements, leadings practices, disruptive and transformative technologies. Continued support for the AFMS Clinical Utility Study to include initial analysis of impact of genomic risk data on study participants. Analysis of recruited AF cohorts for diseases and conditions of operational importance. Continued support for research into educational interventions for the proper use of genetic testing within the AFMS and pharmacogenomics research regarding the use of anti-depressants and pain medication within the AFMS. Implementation of genomic education program at USAF testing facility to measure impact of education on genetic test utilization, clinical care, and patient outcomes. Pharmacogenomic demonstration projects at AFMS sites and AF MTFs to test the impact on patient health and healthcare costs. Investigation of methodologies and requirements for Air Force Medical System bioinformatics tools and processes, including the development of the AFMS digital Biobank and the integration of genomic data into clinical workflow through the development of predictive modeling clinical decision support tools that integrate with Electronic Medical			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307C / *Core Force Health Protection R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Records. Continue to develop a high-content, rapid throughput toxicological capability with pluripotent cells allowing for a rapid screening of possible threats in the aerospace environment. ***FY 2017 Plans:*** Continue to evaluate leading causes of missed training time and medical attrition from training, significantly affect military readiness, to improve the health and well-being of trainees and active duty service members; save significant money from the associated medical and non-medical costs, including long-term disability costs; and improve operational readiness by eliminating disruptions in the training pipeline. Continue subject enrollment for analysis of the Chagas disease threat within high-risk military populations and implement force protection measures to decrease exposure risk. Advance force health protection in the area of occupational and environmental health by delivering real time detection and identification of airborne biological health hazards at the detector's point of operation and improving capabilities of Air Force Medical Service Preventive Medicine personnel by providing rapid detection and notification of the presence of infectious disease agents. Continue the development of new strategies for prevention, identification, and treatment of injuries caused by emerging biological, chemical, directed energy and other physical threats. Continue to develop rapid, ruggedized, field-forward methodologies to detect health threats, including the ongoing evaluation of nanoparticle sensing prototypes for infectious disease threat identification and surveillance. Identify new molecular targets (plasma markers) for enhanced detection and prevention. Provide further analysis of genetic, epigenetic, proteomic and pharmacogenetic testing to advance force health protection measures within the AFMS.			
Accomplishments/Planned Programs Subtotals	0.000	1.000	1.500

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307D / *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
307D: *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.000	0.000	1.000	1.500	-	1.500	2.235	2.375	2.463	2.512	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)	0.000	1.000	1.500

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

FY 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
Continue to develop a high-content, rapid throughput toxicological capability with pleuripotent stem-cells allowing for a rapid screening of possible threats in the aerospace environment that includes genetic uncertainty in the risk assessment. Develop and validate devices or methods that are extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Perform comprehensive study of aircraft breathing air quality across the

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307D / *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Air Force fleet to ensure risks are understood and mitigated if needed. Develop capabilities for remote sensing of environmental hazards. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference. Perform assessment of subtle cognitive and respiratory effects of low-level exposures from low-level exposures in the challenging environments associated with AI operations. Continue to study the role of the gut microbiome relevance to deployed airmen health and performance. ***FY 2017 Plans:*** Continue to develop a high-content, rapid throughput toxicological capability with pleuripotent stem-cells allowing for a rapid screening of possible threats in the aerospace environment that includes genetic uncertainty in the risk assessment. Develop and validate devices or methods that are extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Perform comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed. Develop capabilities for remote sensing of environmental hazards. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference. Perform assessment of subtle cognitive and respiratory effects of low-level exposures from low-level exposures in the challenging environments associated with AI operations. Initiate development of automated algorithms that incorporate environmental sensor and risk assessment to determine appropriate mitigation actions in real time as hazards are presented in-flight and in ground operations. Continue to study the role of the gut microbiome relevance to deployed airmen health and performance.			
Accomplishments/Planned Programs Subtotals	0.000	1.000	1.500

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307D / *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	7.616	4.544	1.180	1.160	-	1.160	1.560	1.640	1.673	1.706	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Expeditionary Medicine Research & Development (Air Force)	4.544	1.180	1.160

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

FY 2015 Accomplishments:

Produced the Clinical Standardization Guidelines for use of progesterone in the treatment of Traumatic Brain Injury (TBI). Transitioned hydroxocobalamin as a safe, FDA approved, effective drug to reduces nitric oxide, improve blood pressure and cardiac output, improve inflammation and act as a neuroprotective agent for septic shock, cyanide induced shock and hemorrhage shock. Concluded in-theatre data enrollment of prehospital and en route analgesic use in traumatically injured patients, including number of procedures, type of procedures, effectiveness, perceived necessity and the complication rates of the attempted or performed procedures. Initiated evaluation of new treatments to decrease deaths associated with acute kidney disease (AKI). Developed a model of Aortic Hemostasis and Resuscitation (AHR) to evaluate Advanced Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA-A) for non-compressible torso hemorrhage and reversal of hemorrhage induced traumatic cardiac arrest (HiTCA). Established model to evaluate endovascular devices for repair of infrarenal aortic injury to reduce mortality due to

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
major vascular injury from noncompressible torso hemorrhage (NCTH) as the leading cause of potentially survivable trauma on the battlefield. Evaluated the abdominal aortic tourniquet application, Tactical Combat Casualty Care (TCCC) guided resuscitation and spray-dried plasma resuscitation on cardiovascular function, cardiopulmonary function and visceral tissue oxygenation to mitigate mortality due to non-compressible, pelvic junctional hemorrhage following traumatic high bilateral extremity amputation and pelvic disruption. Developed a model of bi-lateral hind limb ischemia reperfusion injury using endovascular balloon, occlusion will be developed. Characterized the immune-inflammatory and coagulation responses of traumatic hemorrhage to identify targets of FDA approved immune-inflammatory cloaking compounds that could reduce mortality and morbidity of traumatic hemorrhage. Prototyped portable sterilization technology for surgical instruments in remote settings completed and submitted to FDA for clearance.			
FY 2016 Plans: Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, cryopreserved blood products, rhabdomyolysis and ischemia-reperfusion injury. Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Begin studies to test and compare point of care testing devices for field use. Continue identification of biomarkers and development of decision support algorithms which predict the need for life saving interventions. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Investigate lifesaving hemorrhage control product that can be introduced to the field of combat casualty care as lifesaving interventions. Determine the efficacy of advanced hemorrhage control technologies including X-Stat and small bore X-Stat in models of uncontrolled hemorrhage. Evaluate prehospital and En-Route analgesic use in traumatically injured patients to decrease post-treatment morbidity and mortality. Conduct a study evaluating Cytosorb®TM for removing myoglobin in patients with rhabdomyolysis, or the breakdown of skeletal muscle, to decrease death associated in patients with AKI. Demonstrate that AHR with current and future capability O2-carrying fluids (whole blood [WB], and multi-function resuscitation fluid [MRF]) improves return of spontaneous circulation (ROSC) and survival with critical care in an otherwise lethal model of non-compressible torso hemorrhage and reversal of hemorrhage induced traumatic cardiac arrest compared to standard of care. Evaluate the efficacy of the Cytosorb® filter in mitigating the deleterious effects of bi-lateral hind limb ischemia reperfusion. Evaluate key components of blood to optimize initial hemostatic resuscitation and promote casualty stabilization. Characterize the effects of trauma and damage control resuscitation at the molecular level in blood from patients with exsanguination shock. Characterize the effects of pharmacological intervention on complement activation and coagulation. Evaluate the ability of complement inhibitors to reduce mortality and morbidity of trauma and hemorrhagic shock. Evaluate long-term outcomes and life-long follow-up of the injured Service Member with vascular injury to address late repair success and functional outcomes. Evaluate improved method for AKI prediction for rapid identification of patients at high risk of AKI with subsequent risk of death. In the context of evolving doctrine involving delayed evacuation times, this information is vital in order to prioritize patients for aeromedical evacuation and in the			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
allocation of scarce resources in the deployed environment. Investigate the near and long-term microvascular damage on normal intimal tissue caused by thoracic endograft stents as the first endovascular therapeutic modality for aortic tears. Evaluate the efficacy of Extra-corporeal life support technologies for "suspended animation" approaches that apply both pharmacological and physiological modalities for reducing the impact of metabolism and cellular damage following traumatic injury. Establish Swine Mesenchymal Stromal Cell Library for use in pre-clinical and translational research pertaining to acute lung injury and adjunct therapies for "suspended animation" technologies. Determine efficacy of Adenosine, lidocaine and magnesium (ALM)/Adenocaine in reducing or ameliorating physiologic dyshomeostasis induced by severe controlled hemorrhage to augment "suspended animation" technologies like deep hypothermia in a small volume, lyophilizable and environmentally stable format. ***FY 2017 Plans:*** Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, cryopreserved blood products, rhabdomyolysis and ischemia-reperfusion injury. Continue studies to test and compare point of care testing devices for field use. Continue identification of biomarkers and development of decision support algorithms which predict the need for life saving interventions. Begin FDA approval process for mature decision support algorithms. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Continue to evaluate novel hemorrhage control products that utilize alternative technologies to active hemostatic coatings to provide a lower-cost, safer and more versatile solution to various hemorrhage control pathologies across the continuum of care. Demonstrate feasibility of training AHR to Level II/III emergency care providers to increase survivability of hemorrhage induced traumatic cardiac arrest.			
Accomplishments/Planned Programs Subtotals	4.544	1.180	1.160

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 308C / *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
308C: *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	0.000	0.000	1.503	1.500	-	1.500	1.497	1.501	1.531	1.562	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)	0.000	1.503	1.500

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

FY 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
Investigate lifesaving hemorrhage control product that can be introduced to the field of combat casualty care as lifesaving interventions. Determine the efficacy of advanced hemorrhage control technologies including X-Stat and small bore X-Stat in models of uncontrolled hemorrhage. Evaluate prehospital and En-Route analgesic use in traumatically injured patients to decrease post-treatment morbidity and mortality. Conducted a pilot study evaluating Cytosorb®TM for removing myoglobin in patients with rhabdomyolysis, or the breakdown of skeletal muscle, to decrease death associated in patients with AKI. Demonstrate that AHR with current and future capability O2-carrying fluids (whole blood [WB], and multi-function resuscitation

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308C / *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
fluid [MRF]) improves return of spontaneous circulation (ROSC) and survival with critical care in an otherwise lethal model of non-compressible torso hemorrhage and reversal of hemorrhage induced traumatic cardiac arrest compared to standard of care. Evaluate the efficacy of the Cytosorb® filter in mitigating the deleterious effects of bi-lateral hind limb ischemia reperfusion. Evaluate key components of blood to optimize initial hemostatic resuscitation and promote casualty stabilization. Characterize the effects of trauma and damage control resuscitation at the molecular level in blood from patients with exsanguination shock. Characterize the effects of pharmacological intervention on complement activation and coagulation. Evaluate the ability of complement inhibitors to reduce mortality and morbidity of trauma and hemorrhagic shock. Evaluate long-term outcomes and life-long follow-up of the injured Service Member with vascular injury to address late repair success and functional outcomes. Evaluate improved method for AKI prediction for rapid identification of patients at high risk of AKI with subsequent risk of death. In the context of evolving doctrine involving delayed evacuation times, this information is vital in order to prioritize patients for aeromedical evacuation and in the allocation of scarce resources in the deployed environment. Investigate the near and long-term microvascular damage on normal intimal tissue caused by thoracic endograft stents as the first endovascular therapeutic modality for aortic tears. Evaluate the efficacy of Extra-corporeal life support technologies for "suspended animation" approaches that apply both pharmacological and physiological modalities for reducing the impact of metabolism and cellular damage following traumatic injury. Establish Swine Mesenchymal Stromal Cell Library for use in pre-clinical and translational research pertaining to acute lung injury and adjunct therapies for "suspended animation" technologies. Determine efficacy of Adenosine, lidocaine and magnesium (ALM)/Adenocaine in reducing or ameliorating physiologic dyshomeostasis induced by severe controlled hemorrhage to augment "suspended animation" technologies like deep hypothermia in a small volume, lyophilizable and environmentally stable format. FY16 program cost is $2.047M, UFR = $0.544			
FY 2017 Plans: Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, rhabdomyolysis and ischemia-reperfusion injury. Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Continue to evaluate novel hemorrhage control products that utilize alternative technologies to active hemostatic coatings to provide a lower-cost, safer and more versatile solution to various hemorrhage control pathologies across the continuum of care. Demonstrate feasibility of training AHR to Level II/III emergency care providers to increase survivability of hemorrhage induced traumatic cardiac arrest. FY17 program cost is $2.000M, UFR = $0.5000M			
Accomplishments/Planned Programs Subtotals	0.000	1.503	1.500

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308C / *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308D / *Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
308D: *Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.000	0.000	1.502	1.499	-	1.499	1.497	1.500	1.530	1.561	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)	0.000	1.502	1.499

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

FY 2015 Accomplishments:
No Funding Programmed.

FY 2016 Plans:
Establish the optimal timing to establish a capability when and where needed as expected to meet the "golden hour" requirement and hold patients until movement is available, stabilize and treat during transport, and provide effective, integrated health service support (HSS) across service lines. Assess what resuscitation goals (e.g. evidence-based markers) are required during various phases of patient movement and different patient conditions to improve outcomes.

FY 2017 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 308D / *Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Develop, validate and implement a suite of medical technologies to induce a state of physiology in combat casualties that allows for stabilization and transport without degradation of physiologic status and increases in mortality and morbidity commonly associated with extended pre-hospital transport times in austere combat theaters of operation.			
Accomplishments/Planned Programs Subtotals	0.000	1.502	1.499

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 309A / *Regenerative Medicine (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
309A: *Regenerative Medicine (USUHS)*	13.908	8.388	9.489	7.323	-	7.323	7.373	8.327	10.209	10.413	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Regenerative Medicine (USUHS)	8.388	9.489	7.323

Description: The Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center. The CNRM has established 11 research cores and funded 108 research projects.

FY 2015 Accomplishments:

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

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

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

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Through Nov. 2015, CNRM has published over 180 peer-reviewed publications. In addition, CNRM researchers have presented at numerous national and international conferences. Awarded 10 new research projects in Feb. 2015. In addition, received 46 pre-proposals in response to FY15 proposal call. After scientific screening, 29 were selected to be submitted as full applications, with anticipation of funding 10 new projects in Feb. 2016. Received several recognitions: Clinical Center Directors award to the Phenotyping core for extraordinarily successful efforts in recruitment and retention of patients in the CNRM TBI Natural History study, AlaviMandell Award for Dr. S. Roy's publication entitled,"PET Attenuation Correction Using Synthetic CT from Ultrashort EchoTime MR Imaging," Silver Award of Distinction from the Academy of Interactive & Visual Arts for CNRM communication booklet. ***FY 2016 Plans:*** CNRM objectives include: (1) Continue interdisciplinary, collaborative studies that bring together expertise across USU, WRNMMC, and intramural NIH to address the highest priority TBI research in diagnosis through treatment and recovery as relevant to military service members; (2) Continue operational capability of all Cores to provide efficient research infrastructure with high quality resources and technical expertise; (3)Fund start-up research of one new USU Radiology faculty member to maintain translational neuroimaging capability; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY16 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host internal CNRM data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research;(11) Support fellowship program to facilitate neuroscience and regenerative medicine research capabilities at DoD sites in NCA.; (12) Participate on the Traumatic Brain Injury (TBI) Research Synergy Board (RSB) and contribute to the TBI "Unity of Effort" to strategically strengthen and accelerate TBI research on "America's Health Campus." ***FY 2017 Plans:*** CNRM objectives include: (1) Continue interdisciplinary, collaborative studies that bring together expertise across USU, WRNMMC, and intramural NIH to address the highest priority TBI research in diagnosis through treatment and recovery as relevant to military service members; (2) Continue operational capability of all Cores to provide efficient research infrastructure with high quality resources and technical expertise; (3)Fund start-up research of one new USU Radiology faculty member to			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
maintain translational neuroimaging capability; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY17 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host internal CNRM data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research;(11) Support fellowship program to facilitate neuroscience and regenerative medicine research capabilities at DoD sites in NCA.; (12) Participate on the Traumatic Brain Injury (TBI) Research Synergy Board (RSB) and contribute to the TBI “Unity of Effort” to strategically strengthen and accelerate TBI research on “America’s Health Campus.”			
Accomplishments/Planned Programs Subtotals	8.388	9.489	7.323

C. Other Program Funding Summary ($ in Millions)

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

Remarks

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

D. Acquisition Strategy

N/A

E. Performance Metrics

Center for Neuroscience and Regenerative Medicine: In FY15 through FY17, identify, design protocols, perform scientific and program reviews, and conduct research in Clinical Core activities such as Phenotyping, Imaging and Imaging Analysis, to aid in patient diagnosis and evaluation.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373A / *GDF - Medical Technology Development*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
373A: *GDF - Medical Technology Development*	296.680	99.064	116.294	139.454	-	139.454	134.790	147.378	147.764	149.276	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development provides funds for promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small-scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. Medical technology development is managed by six Joint Program Committees (JPCs): 1- Medical simulation and information sciences (JPC-1) research aims to coordinate health information technology, simulation, and training research across the Medical Health System. Technology development efforts are directed toward the medical simulation task. 2- Military infectious diseases (JPC-2) research is developing protection and treatment products for military relevant infectious diseases. Technology development efforts are directed against tasks in bacterial diseases, diagnostics development, and viral diseases. 3- Military operational medicine (JPC-5) research goals are to develop and validate medical countermeasures against operational stressors, prevent physical and psychological injuries during training and operations, and to maximize health, performance and fitness of Service members. Technology development efforts are directed against tasks in musculoskeletal injury; brain health and performance risk; behavioral health, wellness and resilience; warfighter physical performance; nutrition and weight balance; psychiatry and clinical psychology disorders; neurosensory performance, injury and protection; blunt, blast and accelerative injury; environmental toxicant exposure; and aircrew health and performance. 4- Combat casualty care (JPC-6) research is optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through enroute and facilities care. Technology development efforts are directed against tasks in hemorrhage, shock, and coagulopathy of trauma; TBI neurotrauma and brain dysfunction; treatments for extremity trauma, tissue injury, craniomaxillofacial injury, lung injury, and burns; pre-hospital tactical combat casualty care; enroute care; and military medical photonics. 5- Radiation health effects (JPC-7) research focuses on core capabilities to support technology development of radiation medical countermeasures development, to include demonstration of improved survivability after treatment with selected therapeutic candidates for acute radiation exposure, and identifying radioprotectants (preventative treatment) for further development. 6- Clinical and rehabilitative medicine (JPC-8) is developing knowledge and materiel products to reconstruct, rehabilitate, and provide care for injured Service members. Technology development efforts are directed against tasks in neuromusculoskeletal rehabilitation, pain management, regenerative medicine, and sensory systems. As research efforts mature, the most promising will transition to advanced concept development funding, PE 0604110. For knowledge products, successful findings will transition into clinical practice guidelines.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: GDF – Medical Technology Development	99.064	116.294	139.454
Description: Funds provide for the development of medical technology candidate solutions and components of early prototype systems for test and evaluation. Promising drug and vaccine candidates, knowledge products, and medical devices and technologies are selected for initial safety and effectiveness testing in small scale human clinical trials.			
FY 2015 Accomplishments: FY 2015 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
chemical exposures (e.g., permethrin, an insecticide used to treat uniforms). Refined biomarkers of pulmonary health resulting from exposures to toxic substances. Combat casualty care: Hemorrhage researchers conducted non-clinical assessments of new agents to control severe internal bleeding to be administered by first responders at or near the point of injury. Researchers also evaluated the ability to modulate the immune inflammatory response in hemorrhage. TBI Neurotrauma task research screened new TBI diagnostic approaches. The enroute care task conducted research to evaluate enroute care clinical practice guidelines, the clinical impact of a spinal immobilization litter, and the collection of continuous waveform data on transported critical care patients. Treatments for extremity trauma continued to develop a specialized fracture repair product, address treatments for acute lung injury, enhance limb and craniofacial salvage, and improve wound healing by evaluating the immune response 72 hours post injury. The military medical photonics program devised and tested minimally invasive, implanted just below the skin, miniature lactate sensors, which can give almost continuous readings. Sensors have been supplied to the Army Institute for Surgical Research, where preliminary testing on animals has compared favorably to blood sample testing. Almost continuous lactate sensing is important because lactate buildup is an excellent indicator of insufficient oxygen supply to the body. Photochemical tissue bonding (PTB), developed under the program and applied to nerve repair has been transitioned to other funding, and a collaboration was developed with military surgeons at Walter Reed National Military Medical Center.This collaboration resulted in the discovery of a glass which dissolves within minutes in saline and blood for use as a stent in repairing blood vessels using PTB. Clinical and rehabilitative medicine continued efforts and down-selected products for advanced development for neuromusculoskeletal injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Neuromusculoskeletal injury rehabilitation evaluated the safety and effectiveness of candidate medical technologies for restoration and rehabilitation products. Pain management tracked methadone and opioid related adverse events; developed novel treatments to control pain, including battlefield pain, burn pain, neuropathic (nervous system) pain, and chronic pain after amputation; studied modulation of inflammatory cells as an approach to mitigate spinal cord injury neuropathic pain; studied effects of peripherally administered opioids, and developed nerve blocks for knee and hip arthroplasty (joint replacement) in Veterans. Regenerative medicine focused on novel approaches to engineer regeneration and repair of damaged muscle tissue, to repair nerve gap injuries, to repair blood vascular injury, and evaluated methods to prevent tissue rejection of allografts (a tissue graft from a donor). Sensory systems conducted research to verify central auditory processing disorders in blast-exposed Warfighters, evaluated computerized oculomotor vision screening to expedite the diagnosis of TBI-related oculomotor dysfunctions in a military population, tested cochlear implants for active-duty Service members, clinically assessed pharmacotherapy of hidden noise injury toward a molecular understanding of noise-induced hearing loss, developed a			

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Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
portable mild TBI screening device based on evaluation of a patient's gait, assessed ways to prevent noise damage to cochlear synapses, and developed a silica-collagen composite for corneal replacement. ***FY 2016 Plans:*** Medical simulation and information sciences research is completing the virtual tissue advancement research, which provides open source resources to enable developers to create more appropriate virtual tissue simulations. Enroute training research is addressing issues with providing training to care for wounded Service members during transport and transfer between providers. Research evaluating the effectiveness of gaming in virtual environments with combat medics is being investigated. Investigators are researching knowledge oriented medical training metrics that can best translate into reality and be sustained with optimal patient outcomes, providing educators the building blocks to create better trainers in the future and begin the long process of linking evidence-based training to patient outcomes. Medical simulation is exploring advanced adaptive tutors that incorporate adult learning techniques and neuroplasticity models so that medical personnel are not dependent on gadgets and technologies to treat a patient. Efforts towards other predictive markers that likely constitute characteristics between good and poor medical providers are being investigated. To further the advancements in augmented reality technologies for Phase II Option, medical simulation is looking into applications towards medical training that allows for validation and verification on work presently performed. Military infectious diseases research is supporting an intramural collaborative effort focused on a detailed investigation of combat trauma wound microbiology and infections linked to well-characterized clinical data and outcomes. Focus areas include bacterial microbiome within combat wounds, biofilm production and impact, antimicrobial resistance emergence and impact, and commonly observed microbes and their impact. The overarching goal of this collaborative inter-service effort between DoD clinical and research and development groups is to expand understanding of the complex microbiology inherent within combat wounds in order to lead to improved prevention and treatment. Continue ongoing efforts to develop antimicrobials and manage wound infections to identify novel antimicrobial countermeasures as well as better strategies to prevent/treat wound infections. Diagnostic assays for selected bacteria commonly found in wound infections are progressing in development for use on an FDA-approved diagnostic system to enable quicker diagnosis and treatment. These studies are in alignment with the National Strategy for Combating Antibiotic Resistance. Military operational medicine: Define the neurological consequences of acute and repeated low level blast exposures of varying intensity and frequency in order to improve exposure standards. Perform research contributing to improved auditory injury standards for application in health hazard assessments, and for predictive models of military performance. Support the development of guidelines relating to the likelihood of musculoskeletal injury in military training and applicable to operational environments. Develop improved criteria for head supported mass, and multisensory cueing in degraded visual environments for fixed wing aircraft. Incorporate behavioral intervention regimens into clinical practice guidelines for the treatment of alcohol			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
and substance abuse. Compare cognitive behavioral interventions, which focus on examining the relationships among thoughts, feelings and behaviors for the treatment of PTSD to current standards of care. Conclude two large scale projects evaluating compressed treatment delivery (daily psychotherapy as compared to once per week) for PTSD for equivalency between 3-week versus 3-4 month treatment regimens. Initiate large scale study for pre-/post-biomarker changes associated with psychopharmacologic, psychotherapy, and brain stimulation interventions. Refine PTSD blood-based biomarkers for transition to advanced development. Deliver validated interventions for enhanced resiliency in military families and Warfighters and more accurate suicide prevention screening tools. Develop recommendations on dietary supplement interventions to promote resiliency and sustainment of cognitive performance after brain injury. Transition policy recommendations to the Services for improving Warfighter nutrition during training and operations. Incorporate decision aids for managing thermal physiological work strain into physiological health status monitoring. Develop strategies to mitigate adverse health and disease outcomes of chemical exposures. Validate stress response biomarkers of pulmonary health resulting from exposures to toxic substances. Combat casualty care: Hemorrhage researchers are evaluating immune system modulating drugs to treat hemorrhagic shock; work is aimed at validating diagnostic and therapeutic targets for coagulopathy of trauma. TBI neurotrauma task research is starting to validate a multi-site collaborative TBI endpoints study to improve clinical trial design to inform/accelerate FDA approval of TBI diagnostic tools and therapeutic agents. Treatments for Tissue Injury continues to develop a specialized fracture repair product, address treatments for acute lung injury, enhance limb and craniofacial wound stabilization. Forward Surgical and Critical Care continues to develop the Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) which recently gained FDA approval, for the treatment of acute life-threatening hemorrhage. Forward Surgical and Critical Care also continues to develop technology to detect cardiovascular collapse. Enroute care research is studying the physiological impact of patient transport and appropriate time to transport injured patients following injury. Military medical photonics is developing technologies that focus on the use of advanced optical technologies, including lasers, spectroscopy, and imaging to develop new kinds of diagnostic and therapeutic tools. The readout system for the lactate sensor is being redesigned for greater simplicity, longer life, and to eliminate the need for an internal battery. Commercialization of PTB for multiple clinical applications is being explored. Radiation health effects research begins technology development efforts in FY 2016 to evaluate ARS therapeutic candidates for acute radiation exposure and to develop data to support preparation of a technical data package as detailed in the Code of Federal Regulations, Chapter 21, Part 312. Clinical and rehabilitative medicine is transferring current efforts and down-selecting products to industry for neuromusculoskeletal injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Supporting development of preclinical and pilot/early-phase clinical evaluations of candidate technologies for restoration, regeneration, rehabilitation, and reintegration strategies and medical products. Neuromusculoskeletal injury is continuing research efforts focused on rehabilitation and reintegration strategies and devices; prosthetics (devices that restore function);			

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
found in wound infections for use on an FDA-approved diagnostic system to improve pathogen identification times, which will guide better treatment approaches Program announcements in developing antimicrobials and treating wound infection will be released to address critical research focus areas such as the ability to predict infection and better treatment options for infections with multi-drug resistant organisms. These studies are in alignment with the National Strategy for Combating Antibiotic Resistance. Military operational medicine: Researchers will collect data to validate whole body models of blast injury exposure, and develop criteria to determine the optimal spacing of blast exposures to prevent cumulative mild TBI. Will continue research to develop improved predictive auditory injury models in order to update acoustic injury standards for health hazard assessment. Will begin development of tools to optimize return to duty after lower extremity (foot and ankle) injury, and head supported mass acute and chronic injury predictive models for mounted and dismounted environments. Collect data to improve multisensory cueing criteria for aircrew performance optimization in degraded visual environments. Will utilize data collected in longitudinal assessments for dietary supplement use and correlate usage patterns with associated negative and positive health effects. Will evaluate the effects of healthy cooking on food choice behaviors, nutritional status, and psychological states in Wounded Warriors and their families. Will continue studies evaluating the physical demands associated with selection to historically male military occupations to develop gender-neutral Military Occupational Speciality assignment standards. Will complete studies to inform alcohol and substance abuse prevention and treatment intervention guidelines. Will continue work to deliver validated interventions for promoting resilience in military families and Service members. Will deliver interventions to prevent suicide behaviors and begin clinical trials to test the efficacy of the interventions. Will conclude several large scale intervention studies evaluating pharmacologic, psychotherapy, and augmented psychotherapy (virtual reality and/or pharmacologic cognitive enhancement) treatments for PTSD. Will continue to build larger scale human PTSD data and specimen banks for meta-analyses, consistent with NRAP guidelines. Will validate candidate biomarkers for exposure to inhaled or ingested toxic substances and begin to develop medical guidance for adverse health risk assessments. Will conduct research to provide validated metrics for optimized operational task performance in extreme environments. Combat casualty care: Researchers within the hemorrhage task will continue to evaluate immune system modulating drugs to treat hemorrhagic shock. Work will also be aimed at validating diagnostic and therapeutic targets for coagulopathy of trauma. Inflammatory modulation work will begin to shift focus to the time period 4 to 72 hours post injury (relevant to prolonged field care). New work in this area will begin to focus on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. TBI neurotrauma task research will continue validating a multi-site collaborative TBI endpoints study to improve clinical trial design to inform/accelerate FDA approval of TBI diagnostic tools and therapeutic agents while taking full advantage of the National Collegiate Athletic Association (NCAA)-DoD grand alliance to study TBI research. Treatments for extremity trauma will continue to develop a specialized fracture repair product and novel fracture stabilization techniques, address treatments for acute lung injury, and stabilization of limb wounds			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
and maxillofacial wounds. Forward Surgical and Critical Care will continue to develop the Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA), which recently gained FDA approval, for the treatment of acute life threatening hemorrhage. Forward Surgical and Critical Care also continues to develop technology to detect cardiovascular collapse. In addition, pre-hospital research will be transitioning to advanced development, including the vascular shunt and decision-assisted tools for pre-hospital and intensive care units. The enroute care task will develop the specifications of an integrated system to support safe patient care and hand-offs, and the development of expanded enroute care interventions and treatment capabilities, to include non-invasive monitoring technologies. The military medical photonics program will develop light-based technologies and systems for combat casualty care and transition to advanced development. Particular emphasis will be on creating a portable platform for photo-acoustic imaging, and demonstrating its application to detecting blood pooling in the abdomen and oxygen content in the pulmonary artery. Photochemical cross-linking (the use of light to create new molecular bonds) to strengthen veins for grafting to arteries in wounded warrior surgery will be demonstrated, as will the post-surgical benefits of photochemical bonding (the use of light to create new molecular bonds) in reducing scarring and adhesions. A general theme of the medical photonics program will be to develop miniaturized sensors and actuators which can be inserted or implanted for important new kinds of diagnostic and therapeutic benefit. Radiation health effects research will continue to evaluate ARS therapeutic candidates and radioprotectants for acute radiation exposure and develop data to support preparation of a technical data package, as detailed in the Code of Federal Regulations, Chapter 21, Part 312. Efforts will demonstrate general military utility. Research will develop data to support qualification of models for use in FDA approved trials. Clinical and rehabilitative medicine will conduct early human trials of promising products, evaluate preclinical safety of promising treatments, and test FDA-licensed products in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and/or sensory systems (hearing, vision, and balance) after traumatic injury. Will support clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation outcomes after service-related injuries. Will evaluate novel therapeutics and devices for pain management. Will evaluate preclinical safety and efficacy of immunomodulatory technologies, skin substitutes to treat burn injury, treatments for volumetric muscle loss, treatments for segmental bone defects, and nerve conduits for nerve injury. Will conduct pre-clinical and early clinical trials to advance diagnosis, restoration and rehabilitation of injured and dysfunctional sensory systems, including vision (total orbit, cornea, retina, optic nerve), hearing (hair cells, tympanic membrane, cochlea, auditory nerve) and balance (vestibular complex).			
Accomplishments/Planned Programs Subtotals	99.064	116.294	139.454

C. Other Program Funding Summary ($ in Millions)

N/A

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

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 378A / *CoE-Breast Cancer Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
378A: *CoE-Breast Cancer Center of Excellence (Army)*	25.042	7.907	7.299	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Breast Cancer Center of Excellence	7.907	7.299	0.000

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

FY 2015 Accomplishments:

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

FY 2016 Plans:

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 378A / *CoE-Breast Cancer Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
of the molecular changes associated with alterations in HER2 expression. Results are leading to a more precise diagnosis and customized treatment plans of patients diagnosed with HER2+ breast cancer. ***FY 2017 Plans:*** No funding programmed. Funding for Breast Cancer Center of Excellence transferred from Army to USUHS starting in FY 2017.			
Accomplishments/Planned Programs Subtotals	7.907	7.299	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 378B / *CoE-Breast Cancer Center of Excellence (USU)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
378B: *CoE-Breast Cancer Center of Excellence (USU)*	0.000	0.000	0.000	9.900	-	9.900	9.088	10.280	10.475	10.685	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Breast Cancer Center of Excellence	0.000	0.000	9.900
Description: Breast Cancer CoE provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.			
FY 2015 Accomplishments: No funding programmed.			
FY 2016 Plans: No funding programmed.			
FY 2017 Plans: The Uniformed Services University of the Health Sciences (USUHS) will assume the research oversight of the Breast Cancer Center of Excellence (CoE) beginning in FY 2017.The Breast Cancer CoE will continue to enhance active duty female readiness through study of the increased breast cancer incidence rate in the active duty force by the process of banking biospecimens in the DoD's biorepository, using the repository for intramural/extramural collaborations and secondary usage research. Will use our unique collection of breast cancer biospecimens to study angiogenesis and lymphogenesis in different grades of Ductal Carcinoma In Situ (DCIS) and Invasive Ductal Carcinoma (IDC). Will continue using scientific research to produce better outcomes for our patients (DoD Active Duty, Beneficiaries and Retirees). Will further develop an analytical system for integrative data analysis and mining, and develop a breast knowledgebase to support clinical and research activities in the Breast Cancer CoE/Clinical Breast Cancer Program (CBCP). Will conduct quantitative analysis of therapy relevant proteins by immunohistochemistry within subclasses of breast cancer to provide better patient selection into clinical trials for targeted and combination therapies. Will use state-or-the-art 3D cell culture techniques and modern approaches to study cancer cell biology, study the mechanisms of cell invasion, migration and ultimately metastasis in breast cancer cell lines.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 378B / *CoE-Breast Cancer Center of Excellence (USU)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
The Breast Cancer CoE will identify genetic changes in low- and high-grade breast tumors to improve our understanding of the evolutionary process of breast cancer and to identify a protein signature that can discriminate low- from high-grade breast tumors, allowing for more accurate diagnosis and risk assessment. Will continue to incorporate the rapidly growing public genomic and proteomic datasets related to breast cancer into our data warehouse to be able to mine the combined data sets for the generation of new hypotheses regarding breast cancer development, progression and treatment. Will further collaborations with innovative, mass spectrometric technology companies, such as BERG in support of proteomic profiling of breast cancer tumors and find ways to improve the diagnostic stratification and treatment of women with breast cancer. Our overall mission in FY17 will be to strengthen our capacity to understand, diagnose, and prevent the occurrence of the particularly virulent forms of breast cancer which strike the active duty force disproportionately, thereby affecting military readiness.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	9.900

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 379A / *CoE-Gynecological Cancer Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	22.132	6.909	6.377	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Gynecological Cancer Center of Excellence (Army)	6.909	6.377	0.000

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

FY 2015 Accomplishments:

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 379A / *CoE-Gynecological Cancer Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
biobehavorial intervention to reduce stress and anxiety versus a monitoring and information intervention on progression-free and survival in ovarian cancer with evaluations of biomarker changes in serial biofluids was developed and opened to accrual. ***FY 2016 Plans:*** The Gynecological Cancer Center of Excellence is conducting both discovery and validation studies of predictive and clinically relevant biomarkers and molecular targets for the treatment and management of ovarian and endometrial cancers, evaluates the effect of stress intervention on the recurrence of ovarian cancer, works with the Walter Reed National Military Medical Center Cancer Risk and Prevention Clinic to develop a Clinical Practice Guideline for cancer screening and prevention in patients with hereditary cancer risk syndromes, performs prospective, retrospective, longitudinal and preclinical evaluations of external and host factors as well as biomarker panels to advance early detection, prevention, management and treatment of gynecological malignancies and is developing strategies to overcome chemotherapy drug- and radiation-resistance in gynecologic cancer cells. The program seeks to understand the initiation of gynecological cancer at its molecular origins by evaluating genes that turn on and off cancer development with a focus on the tumor suppressor genes ARID1A, BRCA1/2 and p53. Additionally we are investigating inhibitors of DNA damage response signaling, specifically the ATR protein kinase (an enzyme with a specific gene), to enhance treatment efficacy of multiple modalities of cancer treatment. The program is developing assays for clinical and cancer biomarkers that have diagnostic, prognostic, predictive and therapeutic value. Specific focus is being given to biomarkers for early detection as well as for prediction of risk of death, disease progression, treatment resistance, and therapeutic response. The program seeks to directly impact clinical care and outcome by furthering our laboratory studies of the therapeutic FOLR-I peptide vaccines, E39 and J65 with GM-CSF developed in collaboration with the COE, as well as clinical trials and window trials evaluating combinations and novel therapeutics in gynecological cancers. Furthermore, chemoprevention efforts focus on development of progestin- Vitamin D combinations and surrogates as well as ways to include metformin and statins in prevention-based preclinical studies and prevention trial. Inflammatory cytokines, chemokines as well as tumor-derived and circulating biomarkers are being examined in clinical trials and our randomized intervention trial. Robust tissue and data collection continues to support all of our long term research goals and objectives. ***FY 2017 Plans:*** No funding programmed. Funding for Breast Cancer Center of Excellence transferred from Army to USUHS starting in FY 2017.			
Accomplishments/Planned Programs Subtotals	6.909	6.377	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
379B: *CoE-Gynecological Cancer Center of Excellence (USU)*	0.000	0.000	0.000	8.655	-	8.655	7.943	8.987	9.158	9.341	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Gynecological Cancer Center of Excellence	0.000	0.000	8.655

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

FY 2015 Accomplishments:
No Funding Programmed.

FY 2016 Plans:
No Funding Programmed.

FY 2017 Plans:
The FY 2017 program will build on the foundational elements of investigating gynecological carcinogenesis (the initiation, progression, and metastatic spread of cancer) and drug resistance, developing and deploying clinical biomarkers and assays, and improving clinical care and outcome through evaluations of novel therapeutics, prevention strategies, assessments and interventions in gynecological oncology using pre-clinical studies and clinical trials. These efforts are motivated by bench to bedside translation and clinical application emphasizing early detection, molecular profiling and integrated systems level analysis of gynecological malignancies that will have a major impact on diagnosis, treatment efficacy as well as assessment of prognosis, response to treatment, and disease monitoring. Members of the GYN-COE collaborate in populations-based investigations of risk, outcome, natural history, lifestyle, staging and treatment in gynecological oncology to inform the design, evaluation, analysis, interpretation and ultimate deployment of novel biomarkers, next generation assays, therapeutics, prevention strategies, assessments and interventions in gynecological oncology. Focus will turn to further testing of actionable events and targets in the pathways leading to cancer through both animal modeling with potential for human trials conducted through external partners. Biomarker-based assays for early detection, response to therapy and patient outcome will be tested in robust external data sets

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
to prepare for prospective human testing, and when merited in window trials as well as prospective clinical trials. Utilizing the continually growing Tissue and Data Network with our associated biorespository and data center with robust clinical, cancer treatment and outcome data, an array of Registries both public and military-centric and our expanded collaborative network of national and internal investigative multidisciplinary team, we will continue to integrate advances in science, technology, medicine, molecular profiling and integrated systems biology and networking to identify, validate and deploy clinical biomarkers, risk scores, and next generation assays for predicting disease, risk and outcome in gynecological cancer patients, preventing disease, ensuring readiness, containing costs, improving clinical care and outcome in ways that promote dignity, quality, efficacy and impact.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	8.655

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 381A / *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	8.496	3.281	3.520	3.051	-	3.051	2.697	2.914	3.118	3.180	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Integrative Cardiac Health Center of Excellence (Army)	3.281	3.520	3.051
Description: The focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by combining bimolecular research with lifestyle change strategies to detect CVD at an early stage, and identifying markers of increased risk for heart attack in Service members.			
FY 2015 Accomplishments: The Integrative Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), conducted research studies initiated in FY 2013-2014. Data collection from approved FY 2013-2014 protocols was analyzed and synthesized. ICHP continued translating and communicating best practices to the services in order to augment existing clinical practice. Utilizing a Knowledge-to-Action framework, ICHP continued incorporating findings from its studies for new hypothesis generation and development of new protocols for FY 2015- 2019 to expand the use of point-of-care technology in the ICHP model. These new protocols were developed to include whole-genome sequencing for early cardiovascular disease (CVD) detection, and investigating the use of serum biomarker maps for personalized CVD risk assessment in Wounded Warriors.			
FY 2016 Plans:			

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 382A / *CoE-Pain Center of Excellence (Army)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
382A: *CoE-Pain Center of Excellence (Army)*	6.436	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Pain Center of Excellence (Army) examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration. The Pain Center of Excellence is an integral part of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) whose mission is to become a referral center that supports world-class clinical pain services, provides education on all aspects of pain management, coordinates and conducts Institutional Review Board-approved clinical research and Institutional Animal Care and Use Committee-approved basic laboratory and translational pain research, and serves as the advisory organization for developing enterprise-wide pain policy for the Military Health System. In FY15, the Pain CoE funding line is transferred from Army to USUHS.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Pain Center of Excellence (Army)	0.000	0.000	0.000
Description: The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration. ***FY 2015 Accomplishments:*** No funding programmed. Funding transferred to USUHS. ***FY 2016 Plans:*** No funding programmed. Funding transferred to USUHS. ***FY 2017 Plans:*** No funding programmed. Funding transferred to USUHS.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 382A / *CoE-Pain Center of Excellence (Army)*

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 382B / *CoE-Pain Center of Excellence (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
382B: *CoE-Pain Center of Excellence (USUHS)*	0.000	2.484	2.823	2.641	-	2.641	2.822	3.310	3.376	3.445	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Pain Center of Excellence (USUHS)	2.484	2.823	2.641

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

FY 2015 Accomplishments:

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

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 382B / *CoE-Pain Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
and the Veterans Health Administration regarding pain-related issues and support for implementation of the DoD/VHA Pain Management Task Force Report recommendations. DVCIPM presented a briefing to request designation as a Defense Center of Excellence (DCoE) by the CoE Oversight Board. The CoE Oversight Board members voted to recommend DCoE designation of the DVCIPM to the ASD (HA). ***FY 2016 Plans:*** The DVCIPM has developed a 5-year plan for FY15-19 that will focus on further developing the Pain Assessment Screening Tool and Outcomes Registry (PASTOR); to include developing a patient pain registry and biobank. The registry will be leveraged through predictive modeling to assist providers with pain management decision-making. DVCIPM will continue to focus on complementary and integrative pain management (CIPM) through clinical assimilation studies of modalities such as; acupuncture yoga and massage; evaluation of novel analgesics; and interventional technologies for improved pain management. DVCIPM will continue to serve as the MHS's coordinating organization for pain education and clinical policy development, critical to the continued transformation of DoD pain management. ***FY 2017 Plans:*** The DVCIPM has developed a 5-year plan for FY15-19 that will focus on further developing the Pain Assessment Screening Tool and Outcomes Registry (PASTOR); to include developing a pain registry biobank, establishing a research database; and utilizing predictive modeling to assist providers with pain management decision-making. DVCIPM will continue to focus on complementary and integrative pain management (CIPM) through clinical assimilation studies of modalities such as; battlefield acupuncture (BFA), yoga and massage; evaluation of novel analgesics; and interventional technologies for improved pain management.			
Accomplishments/Planned Programs Subtotals	2.484	2.823	2.641

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	21.287	6.303	6.260	7.900	-	7.900	7.250	8.203	8.359	8.526	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: CoE-Prostate Cancer Center of Excellence (USUHS)	6.303	6.260	7.900
Description: The CPDR is at the forefront of "cutting-edge" clinical, basic science and epidemiologic research. The emphasis is on improving diagnosis, prognosis and treatment of prostate cancer involving new modalities such as MRI guided biopsy, gene-based biomarkers, and precision medicine strategies targeting causal gene alterations in prostate cancer. The CPDR multi-center database is a unique programmatic resource, enrolling over 27,500 DoD health care beneficiaries under suspicion for prostate cancer, with longitudinal follow up to 23 years. This database continues to highlight emerging issues in prostate cancer management such e.g., treatment outcomes, racial/ethnic differences, quality of life and discovery of novel molecular prognostic markers. In light of current issues related to overtreatment of early detected prostate cancers and poorly understood biology of prostate cancer, CPDR's long-term biospecimen banks, high-impact discoveries and collaborations are leading towards better diagnostic and prognostic molecular markers and therapeutic targets with promise in improving the management of the disease. The CPDR's health disparity research focus has uniquely benefited from studying a prostate cancer patient cohort, with a high representation of African American men, in an equal-access military health care system. Ground-breaking studies of the most validated prostate cancer gene, ERG, in over 1,500+ patients provide the first definitive information on prostate cancer biology underscoring racial/ethnic differences with potential to enhance personalized medicine. The CPDR's state-of-the-art research infrastructure and framework is providing education and training for over 100 next generation physicians, scientists, medical and graduate students within DoD medical institutions.			
FY 2015 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
• Gene panel for the detection of prostate cancer (patent application).			
Accomplishments/Planned Programs Subtotals	6.303	6.260	7.900

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 398A / *CoE-Neuroscience Center of Excellence (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
398A: *CoE-Neuroscience Center of Excellence (USUHS)*	3.679	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: CoE-Neuroscience Center of Excellence (USUHS)	0.000	0.000	0.000
Description: The Military Clinical Neuroscience Center of Excellence (MCNCoE) is to improve prevention, diagnosis, and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions. The MCNCoE's approach to its goals includes supporting the research potential of military treatment facilities across the DOD system as well as the national capital area, and facilitating a network of collaborations between investigators across these facilities. ***FY 2015 Accomplishments:*** None, MCNCoE research has been merged into the CNRM beginning in FY 2015. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 398A / *CoE-Neuroscience Center of Excellence (USUHS)*

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 429A / *Hard Body Armor Testing (Army)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
429A: *Hard Body Armor Testing (Army)*	1.356	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Hard Body Armor ***Description:*** Develop a surface-mounted sensor system that will add critical dynamic data to the current clay test procedure and develops human skull fracture injury criteria for focused blunt impacts to the human head. ***FY 2015 Accomplishments:*** No Funding Programmed. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.	0.000	0.000	0.000
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 429A / *Hard Body Armor Testing (Army)*

E. Performance Metrics

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

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

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
431A: *Underbody Blast Testing (Army)*	31.867	4.397	2.679	1.869	-	1.869	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Underbody Blast Testing	4.397	2.679	1.869
Description: Will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or IED, and will provide the biomedical basis for the development of a Warrior-representative blast test manikin and associated biomedically-validated injury criteria that can be used to characterize dynamic events and injury risks for live-fire test and evaluation (LFT&E) crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats.			
FY 2015 Accomplishments: The Underbody Blast Testing project continued medical research in the areas initiated in FY 2014 but with the emphasis shifting during the year from non-injurious conditions to those which cause injuries. This enabled the development of initial human injury probability curves that account for influences unique to the military and to the underbody blast environment. All data transitioned into the Warrior Injury Assessment Manikin (WIAMan) project to enable the fabrication of the first and second generation prototype anthropomorphic test devices (ATDs; manikins or crash test dummies). Validation studies contrasted injuries observed in theater			

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
with those created in the testing program to prioritize further research. Emerging medical research data supported the protection technology development and the modeling and simulation initiatives. ***FY 2016 Plans:*** The Underbody Blast Testing project is continuing medical research in the areas initiated in FY 2015 but with the emphasis shifting to perform matched pair testing of the first generation WIAMan prototype. This is enabling a pairwise comparison between the human injury probability curves and the responsiveness of the WIAMan first generation prototype in the military and underbody blast environments. This work is informing the development of whole-body and component injury criteria and the protective technology for use in the underbody blast environment. ***FY 2017 Plans:*** Will continue to develop body region specific injury criteria under blast loading using whole body dynamic data from whole body blast tests. Various hypotheses will be tested to determine how to create the first injury (i.e., fracture) and subsequent severe injuries (i.e., complex fractures). The goal will be to predict injury with enough resolution to make decisions between competing protective equipment. Supported hypotheses from preliminary component testing will be used in finalized tests to generate and update human injury probability (dose-response) curves and injury assessment response curves (cadaver - ATD relationship).			
Accomplishments/Planned Programs Subtotals	4.397	2.679	1.869

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

Performance metrics include the timely transition of actionable medical research from principal investigators for use in the development of the WIAMan UBB test manikin and to benefit the RDT&E protection technology and acquisition community. Actionable medical research includes biofidelity response corridors (BRCs), human injury probability curves (HIPC), and injury assessment reference curves (IARCs). Principal investigators (PIs) will participate in In-Progress Reviews, technical interchange meetings, and theater injury analysis reviews. PIs will publish emerging results in the proceedings of injury biomechanics symposia and in relevant journals. As required, PIs will participate in DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and are subjected to Program Sponsor Representative

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

progress review to ensure that milestones are being met and deliverables will be transitioned on schedule. An external peer review of the medical research will be conducted to ensure the medical research is scientifically valid and suitable for accreditation for use in supporting acquisition decisions.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 448A / *Military HIV Research Program (Army)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
448A: *Military HIV Research Program (Army)*	6.663	5.270	6.589	6.070	-	6.070	6.359	7.360	7.877	8.035	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Military HIV Research Program	5.270	6.589	6.070
Description: The Military HIV Research Program aims to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection.			
FY 2015 Accomplishments: Conducted initial testing in humans for safety and effectiveness at CONUS and OCONUS sites with down-selected HIV-1 multivalent vaccine candidates, either a single vaccine or a combination of several sub-types. Prepared methods for large scale production of vaccine candidates from various world-wide subtypes. These candidates are being used in future large scale clinical studies.			
FY 2016 Plans: Complete large scale production and characterization of selected vaccine candidates. Initiate large scale safety and effectiveness trials with one or more vaccine candidates either as single vaccine or combination of several sub-types representing major world-wide distribution.			
FY 2017 Plans: Will perform an Early Capture HIV Cohort study in Uganda, Kenya and Tanzania with the purpose of characterizing recruitment, retention, HIV prevalence, HIV incidence and biological characteristics of acute HIV infection in high-risk volunteers. Will initiate a human population study that will provide knowledge about the earliest HIV events to provide possible clues in developing an			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 448A / *Military HIV Research Program (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
effective HIV vaccine or help identify ways to achieve a functional cure. Will test extended safety/dosing/immunogenicity studies with the best combination vaccine candidate.			
Accomplishments/Planned Programs Subtotals	5.270	6.589	6.070

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 830A / *Deployed Warfighter Protection (Army)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
830A: *Deployed Warfighter Protection (Army)*	14.226	4.156	5.306	4.889	-	4.889	5.123	5.930	6.345	6.472	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Armed Forces Pest Management Board (AFPMB), the Deployed Warfighter Protection project plans to develop new or improved protection for ground forces from disease-carrying insects. The focus of this program is to develop new or improved systems for controlling insects that transmit malaria, dengue, chikungunya and other emerging infectious diseases under austere, remote, and combat conditions; understand the physiology of insecticidal activity to develop new compounds with greater specific activity and/or higher user acceptability; examine existing area repellents for efficacy and develop new spatially effective repellent systems useful in military situations; develop new methods or formulations for treating cloth to prevent vector biting; and expand the number of active ingredients and formulations of public health pest pesticides, products and application technologies available for safe, and effective applications. The AFPMB partners with the President's Malaria Initiative and the WHO Global Malaria Program to lead development of new tools for insect-borne disease prevention.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Deployed Warfighter Protection	4.156	5.306	4.889

Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects.

FY 2015 Accomplishments:

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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 830A / *Deployed Warfighter Protection (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
products, DWFP priorities included knowledge products that support vector control and disease risk reduction to include improving current practices used in the field. ***FY 2016 Plans:*** In FY 2016 the Deployed Warfighter Protection (DWFP) research project is developing tools that enable deployed forces to better protect themselves and control biting insects, primarily mosquitoes and sand flies, which transmit force degrading diseases. This is being accomplished through research, testing and evaluation of products, patent submissions, licensing, and EPA registrations for new insecticides. The DWFP is maintaining its focus on personal protection systems, new insecticides, and vector control/insecticide application technologies. For enhanced personal protection systems, protective clothing efforts are being reviewed pending results of the FY 2015 evaluations of prototype bite proof fabric for commercialization; efficacy testing of the alternative to permethrin for treating combat uniforms is being completed and, if effective, will be submitted to the Armed Forces Pest Management Board (AFPMB) and the EPA for approval and registration. Within this same focus area, under area/spatial repellents, the DWFP is expanding field tests focused on the best performing area/spatial-repellent dispensers evaluated in FY 2015 and is working with the EPA and associated industry partner to pursue EPA registration for military use. For new insecticides, the DWFP is down selecting top performing novel molecular pesticides tested in FY 2015 for expanded field testing; conducting faster, more efficient, lab based screening of potential plant-derived and synthetic insecticides to identify promising candidate compounds; and is executing field evaluations of insecticides identified in FY 2015. For vector control/insecticide application technologies, lab and field testing of insecticide sprayer products identified as promising tools in FY 2015 are being conducted with a focus on remotely operated and/or autonomous spraying capabilities. Best performing products/sprayers and technologies tested in FY 2015 are transitioning to industry partners for commercialization and submission to the AFPMB for addition to the National Stock System. ***FY 2017 Plans:*** In FY 2017 the Deployed Warfighter Protection (DWFP) research project will lead translational research to develop and field tools that protect against emerging infectious disease threats and enable deployed forces to better protect themselves from biting insects, primarily mosquitoes and sand flies, which transmit force degrading diseases. This will be accomplished through research, testing and evaluation of products, patent submissions, licensing, and EPA registrations for new insecticides and bite protection tools. The DWFP will maintain its focus on three priority areas: personal protection systems, new insecticides, and vector control/insecticide application technologies. For enhanced personal protection systems, protective clothing technology (bite proof fabric) will be patented and will transition to the US Army Natick Soldier Research, Development and Engineering Center for advanced development; pending results of efficacy testing and EPA registration of the alternative to permethrin for treating combat uniforms, technology will transition to the Services for incorporation into future combat uniforms. Within this same focus area under area/spatial repellents, FY 2016 results and EPA registration of transfluthrin will drive commercialization strategies and licensing agreements for fielding an area/spatial-repellent device to provide passive protection from mosquito biting. In the insecticides development portfolio, the exploration of natural/biopesticides with improved environmental and human safety profiles			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 830A / *Deployed Warfighter Protection (Army)*

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

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Develop, mature and field new or improved products and strategies that protect US forces from disease-carrying insects. Secure registered trademarks, patents, commercial partners, and/or EPA registration of new or improved insecticides, application technologies and repellent systems. Continue to partner with industry to field products and coordinate with the Services and relevant Program Executive Offices (PEOs) to transition efforts.

E. Performance Metrics

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