Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Defense Health Agency											Date: February 2018	
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 2017**	**FY 2018**	**FY 2019 Base**	**FY 2019 OCO**	**FY 2019 Total**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**	**Cost To Complete**	**Total Cost**
Total Program Element	4,918.428	1,345.413	245.936	274.920	-	274.920	269.421	269.473	274.476	279.875	Continuing	Continuing
300A: *CSI - Congressional Special Interests*	3,880.681	1,119.872	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
238C: *Enroute Care Research & Development (Budgeted) (AF)*	12.973	5.669	4.479	6.833	-	6.833	8.088	8.249	8.418	8.586	Continuing	Continuing
238D: *Core Enroute Care R&D - Clinical Translational Focus (AF)*	0.997	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
238E: *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.997	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
243A: *Medical Development (Lab Support) (Navy)*	164.298	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
247A: *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	2.260	2.004	1.548	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	5.812
247B: *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	1.465	1.079	1.238	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	3.782
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	10.245	3.471	5.327	5.523	-	5.523	5.633	5.745	5.859	5.976	Continuing	Continuing
284C: *Core Human Performance R&D - Clinical Translational Focus (AF)*	1.003	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
284D: *Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)*	1.002	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	16.914	6.194	2.699	4.702	-	4.702	5.514	5.624	5.736	5.851	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Defense Health Agency										Date: February 2018		
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)*	0.929	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
285C: *Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.928	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	46.948	9.192	9.504	9.725	-	9.725	9.919	10.118	10.319	10.525	Continuing	Continuing
307C: *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	0.545	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
307D: *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.400	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	13.340	2.206	4.554	4.645	-	4.645	4.737	4.833	4.929	5.028	Continuing	Continuing
308C: *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	1.503	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
308D: *Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)*	1.502	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
309A: *Regenerative Medicine (USUHS)*	31.071	9.520	7.373	8.327	-	8.327	10.209	10.413	10.621	10.833	Continuing	Continuing
373A: *GDF - Medical Technology Development*	508.755	135.552	126.790	128.578	-	128.578	130.412	139.561	143.781	146.566	Continuing	Continuing
378A: *CoE-Breast Cancer Center of Excellence (Army)*	39.699	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Defense Health Agency										Date: February 2018		
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	10.552	9.088	10.280	-	10.280	10.475	10.685	10.898	11.116	Continuing	Continuing
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	34.939	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
379B: *CoE-Gynecological Cancer Center of Excellence (USU)*	0.000	9.226	7.943	8.987	-	8.987	9.158	9.341	9.528	9.719	Continuing	Continuing
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	15.032	3.051	2.697	0.000	-	0.000	0.000	0.000	0.000	0.000	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)*	5.094	2.985	2.822	3.310	-	3.310	3.376	3.445	3.514	3.584	Continuing	Continuing
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	33.379	8.443	7.250	8.203	-	8.203	8.359	8.526	8.696	8.870	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)*	38.742	1.869	8.000	10.800	-	10.800	9.200	1.400	0.000	0.000	-	-
448A: *Military HIV Research Program (Army)*	18.026	7.069	6.359	7.360	-	7.360	7.877	8.035	8.196	8.361	Continuing	Continuing
830A: *Deployed Warfighter Protection (Army)*	23.290	5.693	5.123	5.930	-	5.930	6.345	6.473	6.601	6.733	Continuing	Continuing
478: *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*	0.000	0.000	14.766	14.754	-	14.754	18.556	18.639	18.724	19.098	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Defense Health Agency										Date: February 2018		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115DHA *I Medical Technology Development*							
479: *Framingham Longitudinal Study (USUHS)*	0.000	0.000	4.920	4.920	-	4.920	4.920	4.920	4.920	5.018	Continuing	Continuing
499: *MHS Financial System Acquisition*	0.000	1.766	13.456	21.129	-	21.129	5.373	1.971	2.011	2.051	Continuing	Continuing
381: *CoE - Integrative Cardiac Health Care (USUHS)*	0.000	0.000	0.000	2.914	0.000	2.914	3.118	3.180	3.244	3.309	Continuing	Continuing
504: *WRAIR Vaccine Production Facility Research*	-	0.000	0.000	8.000	-	8.000	8.152	8.315	8.481	8.651	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

For the Army Medical Command -

The Underbody Blast (UBB) Testing medical research project provides funds to establish a scientific and statistical basis for evaluating skeletal injuries to vehicle occupants during ground vehicle UBB events. Areas of interest to the Secretary of Defense are medical research that provides an understanding of the human response

and tolerance limits and injury mechanisms needed to accurately predict skeletal injuries to ground combat vehicle occupants caused by UBB events. This enhanced understanding will support the establishment of an improved capability to conduct Title 10 Live Fire Test and Evaluation and to make acquisition decisions.

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.

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

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

In FY 2017, Congressional Special Interest (CSI) funds were added to support peer-reviewed research programs: Amyotrophic Lateral Sclerosis (ALS), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis, Cancer, Lung Cancer, Orthopedic, Spinal Cord, Vision, Traumatic Brain Injury and Psychological Health (TBI/PH), Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer's, Reconstructive Transplant, Tuberous Sclerosis Complex, Duchenne Muscular Dystrophy, Epilepsy, and Tick-borne diseases. CSI funds were also provided for Joint Warfighter Medical Research, Orthotics and Prosthetics Outcomes, Trauma Clinic Research, HIV/AIDS Program Increase, Global HIV/AIDS Prevention, and Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

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

For the Air Force Medical Service (AFMS), medical research and development programs are divided into five primary thrust areas: En-Route care, Expeditionary Medicine, Operational Medicine (in-garrison care), Force Health Protection (FHP) (detect, prevent, threats), and Human Performance. Expeditionary Medicine is focused on care on the battlefield and in field hospitals prior to transporting patients out of theater to CONUS, and studies trauma resuscitation, hemorrhage control, and other life-saving interventions to keep critically wounded patients alive in the golden hour and to the next level of care. The AFMS is the only service transporting patients on long aeromedical evacuation missions. Therefore, the En-Route care thrust area studies include investigation on the impact of transport on patient and providers (including cabin altitude, noise, vibration, and environmental issues affecting physiology on the aircraft), patient safety factors during transport, medical technologies for use during transport, and research to support education and training with simulation for En-Route care providers. The Human Performance thrust

area focuses on optimizing airmen physical and psychological performance, assessing the physical and cognitive demands on the operator (pilot/aircrew), facilitating a safe aviation environment through technology and equipment assessment, and improving/sustaining airmen performance through training. Medical development and biomedical technology investments in FHP seek to deliver an improved FHP capability across the full spectrum of operations with research that prevents injury/ illness through improved identification and control of health risks. Under FHP, sub-project areas include Occupational Hazard Exposure (Includes Flight Hazards and Integrated Risk), Targeted Risk Identification, Mitigation and Treatment (Formerly Pathogen ID and Novel Therapeutics and includes Big Data), FHP Technologies Development and Assessment (Assay and disease detection), and Health Surveillance, Infection, Injury & Immunity. FHP also includes Innovations and Personalized 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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total
Previous President's Budget	220.916	245.936	274.920	-	274.920
Current President's Budget	1,345.413	245.936	274.920	-	274.920
Total Adjustments	1,124.497	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	1,087.454	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	37.043	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2017	FY 2018
Project: 300A: *CSI - Congressional Special Interests*		
Congressional Add: *245A - Amyotrophic Lateral Sclerosis (ALS) Research*	7.248	-
Congressional Add: *293A - Autism Research*	7.248	-
Congressional Add: *296A - Bone Marrow Failure Disease Research*	2.900	-

Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Defense Health Agency	Date: February 2018
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 2017**	**FY 2018**
Congressional Add: *310A - Peer-Reviewed Ovarian Cancer Research*	19.329	-
Congressional Add: *328A - Multiple Sclerosis Research*	5.799	-
Congressional Add: *335A - Peer-Reviewed Cancer Research*	57.987	-
Congressional Add: *336A - Peer-Reviewed Lung Cancer Research*	11.597	-
Congressional Add: *337A - Peer-Reviewed Orthopaedic Research*	28.994	-
Congressional Add: *338A - Peer-Reviewed Spinal Cord Research*	28.994	-
Congressional Add: *339A - Peer-Reviewed Vision Research*	14.497	-
Congressional Add: *352A - Traumatic Brain Injury/Psychological Health Research*	103.482	-
Congressional Add: *380A - Peer-Reviewed Breast Cancer Research*	115.975	-
Congressional Add: *390A - Peer-Reviewed Prostate Cancer Research*	86.981	-
Congressional Add: *392A - Gulf War Illness Peer-Reviewed Research*	19.384	-
Congressional Add: *396A - Research in Alcohol and Substance Use Disorders*	3.865	-
Congressional Add: *400A - Peer-Reviewed Medical Research*	290.046	-
Congressional Add: *417A - Peer-Reviewed Alzheimer Research*	14.497	-
Congressional Add: *439A - Joint Warfighter Medical Research*	28.359	-
Congressional Add: *452A - Peer-Reviewed Reconstructive Transplant Research*	11.597	-
Congressional Add: *454A - Orthotics and Prosthetics Outcomes Research*	9.665	-
Congressional Add: *456A - HIV/AIDS Program*	12.473	-
Congressional Add: *459A - Peer-Reviewed Epilepsy Research*	7.248	-
Congressional Add: *463A – Program Increase: Restore Core Research Funding Reduction (GDF)*	67.921	-
Congressional Add: *474A – Program Increase: Restore Core Research Funding Reduction (Army)*	108.235	-
Congressional Add: *495 - Peer-Reviewed Tick-Borne Disease Research*	4.832	-
Congressional Add: *496 -Trauma Clinical Research Program*	9.665	-
Congressional Add: *501 - Peer-Reviewed Hearing Restoration Research (Army)*	9.665	-
Congressional Add: *502 - CSI - Peer-Reviewed Kidney Cancer Research (Army)*	9.665	-
Congressional Add: *503 - CSI - Peer-Reviewed Lupus Research (Army)*	4.832	-
Congressional Add: *540A - Global HIV/AIDS Prevention (Navy)*	8.000	-

Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Defense Health Agency	Date: February 2018
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Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2017	FY 2018
Congressional Add: *660A - Tuberous Sclerosis Complex (TSC)*	5.799	-
Congressional Add: *790A - Duchenne Muscular Dystrophy*	3.093	-
Congressional Add Subtotals for Project: 300A	1,119.872	-
Congressional Add Totals for all Projects	1,119.872	-

Change Summary Explanation

- Realigns the management and associated DHP RDT&E resources for the Integrative Cardiac Health Care CoE from Army DHP to USUHS in FY19 and beyond (FY19, $2.914M).
- Realigns funds within existing resources to provide dedicated funding for ongoing medical research at Walter Reed Army Institute of Research (WRAIR) Vaccine Production Facility in FY19 and beyond (FY19, $+8.0M).

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
300A: *CSI - Congressional Special Interests*	3,880.681	1,119.872	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

In FY 2017, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2017 Congressionally-directed research is to stimulate innovative research through a competitive, peer-reviewed research program, and focused medical research at intramural and extramural research sites. Specific peer-reviewed research efforts include the following: Amyotrophic Lateral Sclerosis (ALS), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis, Cancer, Lung Cancer, Orthopedic, Spinal Cord, Vision, Traumatic Brain Injury and Psychological Health (TBI/PH), Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer Research, Joint Warfighter Medical Research, Reconstructive Transplant, Orthotics and Prosthetics Outcomes, HIV/AIDS Program, Epilepsy, Core Research Funding, Tick-borne Disease, Trauma Clinical Research, Global HIV/AIDS Prevention, Tuberous Sclerosis Complex, and Duchenne Muscular Dystrophy. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018
Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research	7.248	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for research in Amyotrophic Lateral Sclerosis (ALS). ALS is a degenerative neurological disorder that causes muscle weakness and atrophy throughout the body. The ALS Research Program is a broadly-competed, peer-reviewed research program with the goal to contribute to a cure for ALS by funding innovative preclinical research to develop new treatments for ALS. Two award mechanisms were released in May 2017, the Therapeutic Development Award and the Therapeutic Idea Award. Applications were received in August 2017 followed by scientific peer review in October 2017. Funding recommendations will be made at programmatic review in January 2018. Awards will be made by September 2018.		
Congressional Add: 293A - Autism Research	7.248	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for Autism research. The Autism Research Program seeks to improve treatment outcomes of Autism Spectrum Disorder (ASD), lead to a better understanding of ASD, and integrate basic science and clinical observations by promoting innovative research. Three award mechanisms were released in June 2017, the Clinical Trial Award, the Clinical Translational Research Award and the Idea Development Award. Applications will be received in October 2017 followed by scientific peer review in January 2018. Funding recommendations will be made at programmatic review in March 2018. Awards will be made by September 2018.		
Congressional Add: 296A - Bone Marrow Failure Disease Research	2.900	-

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for bone marrow failure diseases research. The mission of the Bone Marrow Failure Research Program is to sponsor innovative research that will advance the understanding of inherited and acquired bone marrow failure diseases, and improve the health and life of individuals living with these diseases, with the ultimate goal of prevention and/or cure. This effort has solicited research proposals focused on bone marrow failure syndromes and their long-term effects from the basic science and clinical research sectors. In FY 2017, applications were accepted through one funding opportunity, the Idea Development Award, released in May 2017 . Applications will be received in October 2017 followed by scientific peer review in November 2017. Funding recommendations will be made at programmatic review in January 2018. Awards will be made by September 2018.		
Congressional Add: 310A - Peer-Reviewed Ovarian Cancer Research	19.329	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for ovarian cancer research. In striving to achieve the goal of eliminating ovarian cancer, the Ovarian Cancer Research Program (OCRP) challenges the research community to address high impact, innovative research. The FY 2017 OCRP supported innovative ideas that provide new paradigms, leverage critical resources, facilitate synergistic, multidisciplinary partnerships, and cultivate the next generation of investigators in ovarian cancer. Four award mechanisms were released in May 2017: Pilot Award, Clinical Development Award, Investigator-Initiated Research Award, and the Ovarian Cancer Academy Award recruiting Early-Career Investigators. Applications were received in August 2017 for the Pilot Award and in September 2017 for the remaining three mechanisms. Scientific peer review will be in October 2017. Funding recommendations will be made at the programmatic reviews in December 2017. Awards will be made by September 2018.		
Congressional Add: 328A - Multiple Sclerosis Research	5.799	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for Multiple Sclerosis (MS) research. The mission of the Multiple Sclerosis Research Program (MSRP) is to support pioneering concepts and high-impact research relevant to the prevention, etiology, pathogenesis, assessment, and treatment of MS. The FY 2017 MSRP solicited applications that address Obstacles of Remyelination (nervous system repair) and/or Obstacles to Axonal Protection in MS, Biological Correlates of Disease Activity and Progression in MS, and MS Symptoms (Biology, Measurement, or Treatment). Two award mechanisms were released in June 2017: Exploration Hypothesis Development Award, and Investigator- Initiated Research Award. Applications were received in October 2017 followed by scientific peer review in December 2017. Funding		

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018
recommendations will be made at programmatic review in January 2018. Awards will be made by September 2018.		
Congressional Add: 335A - Peer-Reviewed Cancer Research ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative provided funds for the study of cancers designated by Congress: bladder cancer, brain cancer, colorectal cancer, immunotherapy, Listeria regimens for cancer, liver cancer, lymphoma, melanoma and other skin cancers, mesothelioma (rare form of cancer developed from the protective lining that cover many of the internal organs of the body caused by exposure to asbestos), neuroblastoma, pancreatic cancer, pediatric brain tumors, cancers in children, adolescences and young adults, and stomach cancer. The goal of the Peer-Reviewed Cancer Research Program is to improve the quality of life by decreasing the impact of cancer on Service members, their families, and the American public. Four award mechanisms were released in May and June2017: Career Development Award, Idea Award with Special Focus, Translational Team Science Award, and Expansion. Applications will be received in September 2017 followed by scientific peer review in November/December 2017. Funding recommendations will be made at programmatic review in February 2018. Awards will be made by September 2018.	57.987	-
Congressional Add: 336A - Peer-Reviewed Lung Cancer Research ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative provided funds for lung cancer research. The Lung Cancer Research Program is a broadly-competed, peer-reviewed research program with the goal to eradicate deaths from lung cancer to better the health and welfare of military Service members, Veterans, their families, and the American public. Five award mechanisms were released in May 2017: Career Development Award, Concept Award, Idea Development Award, Investigator-Initiated Translation Research Award, and Translational Research Partnership Award. Applications were/will be received in August and September 2017 followed by scientific peer review in October and November 2017. Funding recommendations will be made at programmatic review in January 2018. Awards will be made by September 2018.	11.597	-
Congressional Add: 337A - Peer-Reviewed Orthopaedic Research ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative provided funds for orthopedic research to advance optimal treatment and rehabilitation from neuromusculoskeletal (bone, muscle, tendon, ligament, nerve, and cartilage) injuries sustained during combat or combat-related activities. The goal of the FY 2017 Peer-Reviewed Orthopaedic Research Program was to provide all Warriors affected by orthopedic injuries sustained in the defense of our Constitution the opportunity for optimal recovery and restoration of function. Five award mechanisms were released in May 2017: Clinical Trial Award, Clinical Translational Research Award,	28.994	-

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018
Integrated Clinical Trial Award, Expansion Award, and Applied Research Award. Pre-applications were received in July 2017 and applications will be received in September 2017, followed by scientific peer review in November 2017. Funding recommendations will be made at programmatic review in January 2018. Awards will be made by September 2018.		
Congressional Add: 338A - Peer-Reviewed Spinal Cord Research ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative provided funds for spinal cord injury (SCI) research. The FY 2017 Spinal Cord Injury Research Program (SCIRP) challenged the scientific community to design research that will foster new directions for and address neglected issues in the field of SCI research with particular focus on three areas: (1) pre-hospital, prolonged field care, en route care, and early hospital management of SCI; (2) development, validation, and timing of promising interventions to address consequences of SCI and to improve recovery; and (3) identification and validation of best practices in SCI. Five award mechanisms were released in June 2017: Clinical Research Development Award, Clinical Trial Award, Investigator-Initiated Research Award, Qualitative Research Award, Translational Research Award. Pre-applications were received August 2017, applications will be received in November 2017, followed by scientific peer review in January 2018. Funding recommendations will be made at programmatic review in March 2018. Awards will be made by September 2018.	28.994	-
Congressional Add: 339A - Peer-Reviewed Vision Research ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative provided funds for vision restoration research. The Peer-Reviewed Vision Research Program supported research targeting the causes, effects and treatments of eye damage, visual deficits due to traumatic brain injury (TBI) and diseases that, despite their different mechanisms of development, all have a common end result -- degeneration of the critical components of the eye and impairment or loss of vision. The results of this research are anticipated to support restoration and maintenance of visual function to ensure and sustain combat readiness and directly benefit the lives of military, Veteran and civilian populations. The FY 2017 Vision Research Program focused on 1- mitigation and treatment of damage to ocular structures and the visual system consistent to military-relevant injuries and diseases incident to military service, 2- vision restoration and regeneration, and 3- knowledge, capabilities, and equipment for early responders to diagnose and mitigate military-relevant eye injuries and diseases in austere or remote environments. Two award mechanisms were released in April 2017: Clinical Trial Award and Technology/Therapeutic Development Award. Applications were received in October 2017, followed by scientific peer review in January 2018, and programmatic review in March 2018. Awards will be made by September 2018.	14.497	-
Congressional Add: 352A - Traumatic Brain Injury/Psychological Health Research	103.482	-

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for research aimed to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and combat-related traumatic brain injury (TBI) on the function, wellness, and overall quality of life, including interventions across the deployment lifecycle for Service members and Veterans, as well as their family members, caregivers, and communities. Key priorities of the FY 2017 Traumatic Brain Injury and Psychological Health (TBI/PH) Research Program were supporting projects aligned with the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service members, and Military Families; enabling significant research collaborations; and complementing ongoing Department of Defense (DoD) efforts to ensure the health and readiness of our military forces by improving upon and optimizing the standards of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In support, the FY 2017 Military Operational Medicine Research Program continued to fund the Military Suicide Research Consortium toward development of state-of-the-art, evidence-based, effective suicide prevention tools and interventions to the DoD. The FY 2016 Combat Casualty Care Research Program initiated studies to inform clinical practice guidelines for the management of TBI by analyzing the Deployed Warrior Medical Management Center and the DoD Trauma Registry casualty treatment data containing Operation Iraqi Freedom/ Operation Enduring Freedom (OIF/OEF) TBI clinical management to determine the best treatment outcome for TBI casualties. Moreover, a clinical study was initiated to validate Virtual Care, Telehealth, and Mobile technology applications to enable far forward medical care for the management of TBI.		
Congressional Add: 380A - Peer-Reviewed Breast Cancer Research	115.975	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for breast cancer research. The Breast Cancer Research Program challenged the scientific community to design research that addresses the urgency of ending breast cancer. Applications were required to address at least one of nine overarching challenges, which were focused on preventing breast cancer, identifying determinants of breast cancer initiation, risk, or susceptibility, distinguishing deadly from non-deadly breast cancers, conquering the problems of over-diagnosis and over-treatment, identifying what drives breast cancer growth and determining how to stop it, identifying why some breast cancers become metastatic, determining how to prevent recurrence, revolutionizing treatment regimens by replacing them with ones that are more effective, less toxic, and impact survival, and eliminating the mortality associated with metastatic breast cancer. Program Announcements for six award mechanisms were released in May and August 2017: Breakthrough Award Levels 1 and 2, Breakthrough Award Levels 3 and 4, Distinguished Investigator Award, Era of Hope Scholar Award, Innovator Award, and Breakthrough Fellowship Award. Application submission deadlines were in June, August, and December 2017,		

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018
scientific peer reviews in August and October 2017 and February 2018, and programmatic reviews in October and December 2017 and January, April, and May 2018. Awards will be made by September 2018.		
Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research	86.981	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for prostate cancer research. The vision for the FY 2017 Prostate Cancer Research Program (PCRP) was to conquer prostate cancer by funding research to eliminate death from prostate cancer and enhance the well-being of men experiencing the impact of the disease. To address the most critical current needs in prostate cancer research and clinical care, the PCRP solicited research applications addressing four overarching challenges: 1- distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer, 2- develop strategies to prevent progression to lethal prostate cancer, 3- develop effective treatments and address mechanisms of resistance for men with high risk or metastatic prostate cancer, and 4- develop strategies to optimize the physical and mental health of men with prostate cancer. In addition, research projects are being solicited in the areas of: data science and analytics; imaging and targeted radionuclide therapy; population science; precision medicine, screening, and surveillance; survivorship, including psychosocial impact on the patient and family; therapy and mechanisms of resistance and response; and tumor and microenvironment biology. Six award mechanisms were released in May 2017: Clinical Consortium Award, Early Investigator Research Award, Health Disparity Research Award, Idea Development Award, Impact Award, Prostate Cancer Pathology Resource Network Award, and Physician Research Award. Applications were/will be received in August, September, and October 2017, followed by scientific peer reviews in October, November, and December 2017. Funding recommendations will be made at programmatic reviews in January and February 2018. Awards will be made by September 2018.		
Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research	19.384	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for Gulf War Illness research. The vision for the FY 2017 Gulf War Illness Research Program was improving the health and lives of Veterans who have Gulf War Illness by funding research to identify effective treatments, improve clinical definition and diagnosis, and to better understand the underlying biology and symptoms of Gulf War Illness. Four award mechanisms were released in May 2016: Biorepository Resource Network Award, Clinical Consortium Award, Investigator-Initiated Focused Research Award, and Qualitative Research Award. Applications will be received in September 2017 followed by scientific peer review in November 2017. Funding recommendations will be made at programmatic review in January 2018. Awards will be made by September 2018.		
Congressional Add: 396A - Research in Alcohol and Substance Use Disorders	3.865	-

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for alcohol and substance use disorders (ASUD) research. The goal of the FY 2017 Alcohol and Substance Abuse Disorders Research Program was to identify and develop new medications to improve treatment outcomes for ASUD, especially related to traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD). A Consortium Award Program Announcement was released in June 2017. Applications were received in September 2017, followed by scientific peer review in November 2017 and programmatic review in Jan 2018. Awards will be made by September 2018.		
Congressional Add: 400A - Peer-Reviewed Medical Research	290.046	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for military-relevant research in Congressionally directed topic areas toward the goal of improving the health and well-being of all military Service members, Veterans, and beneficiaries. The 48 Congressionally-directed topics for FY 2017 were: Acute Lung Injury, Antimicrobial Resistance, Arthritis, Burn Pit Exposure, Chronic Migraine and Post-traumatic Headache, Congenital Heart Disease, Constrictive Bronchiolitis, Diabetes, Diarrheal Diseases, Dystonia, Early Trauma Thermal Regulation, Eating Disorders, Emerging Infectious Diseases, Epidermolysis Bullosa, Focal Segmental Glomerulosclerosis, Fragile X, Guillain-Barre Syndrome, Hepatitis B and C, Hereditary Angioedema, Hydrocephalus, Immunomonitoring of Intestinal Implants, Inflammatory Bowel Disease, Influenza, Integrative Medicine, Interstitial Cystitis, Malaria, Metals Toxicology, Mitochondrial Disease, Musculoskeletal Disorders, Nanomaterials for Bone Regeneration, Non-Opioid Pain Management, Pancreatitis, Pathogen-inactivated Cryoprecipitate, Polycystic Kidney Disease, Post-Traumatic Osteoarthritis, Pulmonary Fibrosis, Respiratory Health, Rett Syndrome, Rheumatoid Arthritis, Scleroderma, Sleep Disorders, Spinal Muscular Atrophy, Sustained-Release Drug Delivery, Tinnitus, Tuberculosis, Vaccine Development for Infectious Disease, Vascular Malformations, and Women's Heart Disease. Five award mechanisms were offered in FY 2017: Clinical Trial Award, Discovery Award, Focused Program Award, Investigator- Initiated Research Award, and Technology/Therapeutic Development Award. For the Discovery Award, application receipt occurred in August 2017, scientific peer review was conducted in August - September 2017, and funding recommendations will be made during programmatic review in November 2017. For the remaining mechanisms, application receipt will occur in October 2017, peer review will be conducted in November - December 2017, and funding recommendations will be made during programmatic review in February 2018. Awards will be made by September 2018.		
Congressional Add: 417A - Peer-Reviewed Alzheimer Research	14.497	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for Alzheimer's disease research. The FY 2017 Peer-Reviewed Alzheimer's Research Program (PRARP) sought to: 1- address		

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018
the long-term consequences of traumatic brain injury (TBI) as they pertain to Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD); and 2- reduce the burden on AD/ADRD-affected individuals and caregivers, especially in the military and Veteran communities. Four award mechanisms were released in July 2017: Convergence Science Research Award, Quality of Life Research Award, New Investigator Award, and Research Partnership Award. Pre-applications will be received in early September 2017, applications in late September 2017, followed by peer review in November 2017. Funding recommendations will be made at programmatic review in February 2018. Awards will be made by September 2018.		
Congressional Add: 439A - Joint Warfighter Medical Research	28.359	-
FY 2017 Accomplishments: The FY 2017 Joint Warfighter Medical Research Program (JWMRP) provides continuing support for promising projects previously funded by Congressional Special Interest (CSI) initiatives. The focus is to augment and accelerate high priority DoD and Service medical requirements that are close to achieving their objectives and yield a benefit to military medicine. The FY 2017 JWMRP supported military medical research in medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care,, and clinical and rehabilitative medicine. For FY17, no advanced development projects were solicited to apply for funding. FY17 JWMRP funding was used to continue support for promising research previously funded through the JWMRP. Awards will be made by September 2018.		
Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research	11.597	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for reconstructive transplantation research. The FY 2017 Reconstructive Transplant Research Program (RTRP) focused on research in reconstructive transplantation for the refinement of approaches for hand, face, and other vascularized composite tissue allografts, which includes multiple body system components such as skin, muscle, tendon, nerves, bone, and blood vessels. In addition, the RTRP focused on research aimed toward improving access to reconstructive transplants, and on immunomodulation strategies that can reduce the need for immunosuppression regimens. Four award mechanisms were released in August 2017: Concept Award, Investigator-Initiated Research Award (IIRA), Technology Development Award (TDA), and Qualitative Research Award (QRA). Preproposal receipt for the IIRA, QRA, and TDA is in September 2017, with invitations to be sent in October 2017. Letter of Intent receipt for the Concept Award is in November 2017. Full application receipt is due in December 2017. Peer review will take place in January 2018, and Programmatic Review will take place in late March or early April 2018. Awards will be made by September 2018.		
Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research	9.665	-

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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 2017	FY 2018
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for orthotics and prosthetics outcomes research. The goal of the FY 2017 Orthotics and Prosthetics Outcomes Research Program was to support research that evaluates the comparative effectiveness of orthotic and prosthetic devices using patient-centric outcomes for Service members and Veterans who have undergone limb amputation. The program was focused on outcomes-based best practices through analysis of the merits of prosthetic and orthotic device potions currently available, and not on the development of new, or the improvement of existing, technology. The program intent was to generate clinically useful evidence to enhance and optimize patient outcomes. One award mechanism wills be released in September 2017: Orthotics and Prosthetics Outcomes Research Award. Pre-applications will be received in October 2017 and applications in January 2018. Scientific peer review will be held in February 2018, and programmatic review will occur in April 2018. Awards will be made by September 2018.		
Congressional Add: 456A - HIV/AIDS Program ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative complemented the funding for the HIV/AIDS research program. Several potential vaccine candidates were down-selected for further testing in human volunteers to study their ability to provoke an immune response that can protect against HIV either as a single vaccine or combination of various subtypes.	12.473	-
Congressional Add: 459A - Peer-Reviewed Epilepsy Research ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative provided funds for traumatic brain injury (TBI)-related epilepsy research. The FY 2017 Peer Reviewed Epilepsy Research Program supported studies to examine the interconnection between TBI and epilepsy in four scientific focus areas: 1-epidemiology, 2- markers and mechanisms of post traumatic epilepsy, 3- models of post-traumatic epilepsy, and 4- research into psychogenic (non-epileptic) seizures. Two Award Mechanisms were released for FY17; the Idea Development Award and Epilepsy Risk Factors Award. Letters of intent and applications were received in September 2017. Peer review will be held in November 2017, and programmatic review in February 2018. Awards will be made by September 2018.	7.248	-
Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative was directed toward FY 2017 DHP core research initiatives in PE 0603115. Funds supported medical technology development efforts in medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, and clinical and rehabilitative medicine (Project 373A).	67.921	-
Congressional Add: 474A – Program Increase: Restore Core Research Funding Reduction (Army)	108.235	-

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018
FY 2017 Accomplishments: This Congressional Special Interest initiative was directed toward the restoral of Army research initiatives in PE 0603115. Funds supported research for the Cardiac Health CoE (381A), Military HIV Research (448A), and Deployed Warfighter Protection (830A).		
Congressional Add: 495 - Peer-Reviewed Tick-Borne Disease Research	4.832	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for tick-borne diseases research. The FY 2017 Peer Reviewed Tick-Borne Disease Research Program's mission was to support research focused on understanding the pathogenesis of Lyme disease and other tick-borne illness and on delivering innovative solutions to prevent and better diagnose and treat their manifestations. Two funding opportunities were released in May 2017: Idea Award and Investigator-Initiated Research Award. Pre-applications were received in July 2017 and applications will be received in October 2017. Scientific peer review will be held in December 2017, and funding recommendations will be made at programmatic review in February 2018. Awards will be made by September 2018.		
Congressional Add: 496 -Trauma Clinical Research Program	9.665	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds for advancing trauma clinical research. Through a competitive Request for Proposals (RFP) process the DoD has created 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 Indefinite Deliverable Indefinite Quantity (IDIQ) contract established the Linking Investigations in Trauma and Emergency Services (LITES) trauma research network. The LITES network creates a standing research consortium of US trauma systems and centers with the capability to conduct prospective, multicenter, injury care and outcomes research of relevance to the Department of Defense. The LITES network is led by the University of Pittsburgh and features nine partnering sites, and the network has to ability to expand or contract based on the research performed. During FY17 an Expert Panel of subject matter experts from the DoD (including representatives from the Combat Casualty Care Research Program of the US Army Medical Research and Materiel Command and the US Army Institute of Surgical Research) and other Federal agencies relevant to the research performed or to be performed by the LITES network was established to support research oversight and generation of task orders. FY17 Congressional Special Interest funding will be used to execute new DoD-relevant research task orders for the LITES network. Awards will be made by September 2018.		
Congressional Add: 501 - Peer-Reviewed Hearing Restoration Research (Army)	9.665	-
FY 2017 Accomplishments: This Congressional Special Interest initiative provided funds to pursue promising, necessary research for treatment of burdensome and very prevalent auditory system injury. The vision of the		

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018
hearing restoration research program is to improve the operational effectiveness, medial readiness and quality of life of Service members and Veterans with auditory system injuries. The mission of the program is to advance the science of hearing restoration by delivering groundbreaking research and solutions that remove barriers to successful treatment of auditory system injury. A Stakeholders Meeting and Vision Setting meeting were held in August 2017. Two program announcements will be released in September 2017 including a Translational Research Award and Focused Research Award. The receipt of all applications is set for the middle of November 2017 with Peer Review in January 2018 and Programmatic Review in March 2018. Awards will be made by September 2018.		
Congressional Add: 502 - CSI - Peer-Reviewed Kidney Cancer Research (Army) ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative provided funds for research into kidney cancer. The vision of the kidney cancer research program is to eliminate kidney cancer. A Stakeholders Meeting and Vision Setting meeting were held in August 2017. Four program announcements will be released in October 2017 including the Idea Development, Concept, Translational Research Partnership, and the Consortium Development Award. The receipt of all applications will be in January 2018 with Peer Review in February 2018 and Programmatic Review in April 2018. Awards will be made by September 2018.	9.665	-
Congressional Add: 503 - CSI - Peer-Reviewed Lupus Research (Army) ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative provided funds for research into lupus. The vision of the Lupus Research Program is to cure lupus through partnership of scientists, clinicians, and consumers. The Stakeholders and Vision Setting Meetings were held in August 2017. Two program announcements will be released in October 2017 including the Concept Award and Idea Award. The receipt of all applications will be in January 2018 with Peer Review in February 2018 and Programmatic Review in April 2018. Awards will be made by September 2018.	4.832	-
Congressional Add: 540A - Global HIV/AIDS Prevention (Navy) ***FY 2017 Accomplishments:*** After receipt of Congressional Add Funding, the funds will be used for Global HIV/AIDS Prevention.	8.000	-
Congressional Add: 660A - Tuberous Sclerosis Complex (TSC) ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative provided funds for Tuberous Sclerosis Complex (TSC) research. The FY 2017 Peer Reviewed Tuberous Sclerosis Complex Research Program (TSCRP) sought to support innovative research to improve the lives of individuals with TSC through understanding the pathogenesis and manifestations of TSC and developing improved diagnostic and treatment approaches. Three award mechanisms were released in May 2017: Idea Development Award, Exploration-	5.799	-

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018
Hypothesis Development Award, , and Clinical Translational Research Award. Applications were received in July 2017, followed by scientific peer review in September 2017. Funding recommendations will be made at programmatic review in November 2017. Awards will be made by September 2018.		
Congressional Add: 790A - Duchenne Muscular Dystrophy ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative provided funds for Duchenne Muscular Dystrophy (DMD) research. DMD is caused by gene mutations in skeletal muscle proteins, and affects approximately 1 in 3,600 boys causing muscle degeneration and eventual death. The goal of the FY 2017 Duchenne Muscular Dystrophy Research Program was to preserve and improve the function and quality of life, and to extend the lifespan of all individuals with Duchenne by supporting research for the discovery, development, and clinical testing of novel therapeutics. Two award mechanisms were released in May 2017: Career Development Award and Investigator-Initiated Research Award. Applications will be received in October 2017 with scientific peer review to be conducted in January 2018 followed by programmatic review in March 2018. Awards will be made by September 2018.	3.093	-
Congressional Adds Subtotals	1,119.872	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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COST ($ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
238C: *Enroute Care Research & Development (Budgeted) (AF)*	12.973	5.669	4.479	6.833	-	6.833	8.088	8.249	8.418	8.586	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 2017	FY 2018	FY 2019
Title: Enroute Care Research & Development (Budgeted) (AF)	5.669	4.479	6.833
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 2018 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 austere, pre-transport, qualitative clinical testing. 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. Evaluate mechanisms for neuroprotection including hydroxocobalamin in a hemorrhagic model of global and traumatic brain ischemia and to understand and therapeutically target the physiological response associated with prolonged field care and extended hold time. Perform service-connected life trajectory comparison of psychiatric aeromedical evacuation and non-psychiatric aeromedical evacuation patients. Establish database for medical evacuation treatment indicators with care and resolution outcomes. Discovery, refinement, and implementation of advanced genetics, epigenetics, and transcriptome technologies to predict resiliency and to enhance point-of-care medical and aeromedical decision making.			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
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. 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 movement. 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. 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. Continue multicenter closed-loop ventilation device trials. Continue to characterize vibration on transport platforms. Continue to investigate medication efficacy at altitude. Continue investigating new research and development requirements based on results of prior studies and warfighter gap analyses. Begin development of an animal-free, human-free tool for testing efficacy and safety of medications and biochemical pain mitigation strategies during aeromedical evacuation flights.			
FY 2019 Plans: FY 2019 plans continue efforts as outlined in FY 2018. In addition, plans are to complete multicenter closed-loop ventilation device trials. Evaluate mechanisms for neuroprotection including hydroxocobalamin in a hemorrhagic model of global and traumatic brain ischemia and to understand and therapeutically target the physiological response associated with prolonged field care and extended hold time. Perform service-connected life trajectory comparison of psychiatric aeromedical evacuation and non-psychiatric aeromedical evacuation patients. Establish database for medical evacuation treatment indicators with care and resolution outcomes. Discovery, refinement, and implementation of advanced genetics, epigenetics, and transcriptome technologies to predict resiliency and to enhance point-of-care medical and aeromedical decision making. Evaluate the influence of altitude, oxygenation, and sedation on neurodegeneration following traumatic brain injury (TBI). Initiate a retrospective study of patients with traumatic brain injury transported by critical care transport team (CCATT). Assess the effects of aeromedical evacuation on the risk of vasospasm following TBI. Continue with developing research objectives and end states focused in the AE PoR Core Capability Areas (CCAs): Clinical En Route Care and Patient Safety; En Route Care Education, Training and Simulation; En Route Care Medical Technologies; Impact of Transport; and Clinical/Patient Decision Support and Monitoring.			
FY 2018 to FY 2019 Increase/Decrease Statement:			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Slight increase due to additional efforts to complete multicenter closed-loop ventilation trials as outlined in the FY 2019 Base plans.			
Accomplishments/Planned Programs Subtotals	5.669	4.479	6.833

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
• BA-1, PE 0807714HP: *Other Consolidated Health Support*	14.259	14.655	-	-	-	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
238D: *Core Enroute Care R&D - Clinical Translational Focus (AF)*	0.997	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

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)

N/A

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 2019 Defense Health Agency											Date: February 2018	
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 2017**	**FY 2018**	**FY 2019 Base**	**FY 2019 OCO**	**FY 2019 Total**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**	**Cost To Complete**	**Total Cost**
238E: *Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.997	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

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)

N/A

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

SEE PROJECT CODE 238C PROGRAM FUNDING SUMMARY FOR PROJECT CODE 238E 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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
243A: *Medical Development (Lab Support) (Navy)*	164.298	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 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 2017	FY 2018	FY 2019
Title: Medical Development (Lab Support) (Navy)	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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
247A: *Elimination of Malaria in Southeast Asia (CARB) (Navy)*	2.260	2.004	1.548	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	5.812

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: Elimination of Malaria in Southeast Asia (CARB) (Navy)	2.004	1.548	0.000

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 2017 Accomplishments:
Enhanced surveillance activities with the Ministry of Health were continued at sites in central Vietnam and on the Laos border. This project has identified risk factors among forest goers, similar to US military personnel in terms of age, health and activity, associated with acquiring malaria. Preliminary data from 2015 and 2016 presented at the American Society of Tropical Medicine and Hygiene (Nov 2016); this information will inform future studies on malaria interventions. To continue work in Vietnam with the Ministry of Health a 2-year work plan was approved in July 2016. Continued recruitment of Vietnam-Australia-US military collaborative study to characterize drug resistance in central Vietnam. Preliminary data, indicating no drug resistance present at study site, presented at the USPACOM Asia Pacific Military Health Exchange in Kuantan, Malaysia (Aug 2016). Cross sectional study protocol approved by Vietnam Ministry of Defense; this project started in Q1 FY17 targeting people served by military clinics in Gai Lia Province, a remote area on the Cambodia border.

FY 2018 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Continuing FY17 work, FY18 funding will support the modeling of collected malaria surveillance and intervention data to measure the impact of previous interventions in Vietnam. The Ministry of Health has agreed in principal to provide malaria data from 2010-2015 to study the impact of environmental, climatic and control/elimination factors on malaria burden. This effort will be enhanced by continuation of ongoing surveillance efforts with the Ministry of Health with expanded collection of blood samples to evaluate current malaria infection by microscopic and PCR detection of malaria parasites and historic malaria exposure by antibody testing. These activities will improve the understanding of malaria parasite diversity and the distribution of drug resistance along the Vietnam-Cambodia-Laos border region. The focus of efforts with the Ministry of Health will be studying malaria transmission within the country and transport of malaria parasites along the Laos-Cambodia-Vietnam border, a new project will be initiated to detect malaria infection in people returning from working in Africa. This project will provide insight into the transport of which may impact malaria transmission patterns in Vietnam. In FY18 efforts with the Ministry of Defense will focus on completing the cross-sectional study approved in FY17. This study will be conducted in Gai Lia Province on the Cambodia border and provide information on subclinical malaria infection. Subclinical infections are not captured in routine surveillance activities; this gap impacts Vietnam's malaria elimination program and US force health protection strategy as these cases are part of the malaria transmission cycle. Clinical studies on malaria drug resistance will continue in FY18. The Ministry of Defense is reviewing a new clinical study for malaria drug resistance in Dak Nong Province on the Cambodia border, this study began in Q3 FY17 and will continue for two years. ***FY 2019 Plans:*** Building on partnerships with the Ministries of Health and Defense surveillance activities will continue in border areas with known malaria drug resistance. Surveillance efforts will be augmented by pilot testing intervention products and packages that could be utilized by the Vietnam National Malaria Control Program and the US DoD to inform malaria prevention and control programs. Surveillance and malaria control/elimination products and strategies will be evaluated using approaches harmonized with the World Health Organization and US DoD Defense Malaria Assistance Program. Study results and recommendations will be reported in refereed professional journals and policy recommendations submitted to the Vietnamese and US Governments. The project will come to an end in FY18/19, therefore, no funding is budgeted in the years following. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** The project will come to an end in FY18/19, therefore, no funding is budgeted in the years following.			
Accomplishments/Planned Programs Subtotals	2.004	1.548	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
247B: *Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)*	1.465	1.079	1.238	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	3.782

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 largest infectious disease hospital in Egypt, Abbassia Fever Hospital, provides critical severe infection and antimicrobial resistance data from the North African Theater. This project supports (both directly and indirectly) Global Health Security Agenda priorities: Combat Antibiotic Resistance Bacteria (CARB); Prevent Avoidable Epidemics; Detect Threats Early; and Respond Rapidly and Effectively to biological threats of international concern

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)	1.079	1.238	0.000
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 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 2017 Accomplishments: FY17 efforts supported continued enrollment of severely ill patients in an observational study in Cambodia at Takeo Provincial Hospital and in Ghana at Komfo Anoyke Teaching Hospital (KATH). 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			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019

infection and evidence of systemic inflammation were considered for enrollment. Laboratory testing augmented the testing routinely performed at the hospital microbiology laboratory, and included diagnostic tests (e.g. blood cultures, malaria smears, HIV tests, and serology), molecular diagnostics, and assays measuring the host-response (RNA sequencing, proteomics, and metabolomics). Sophisticated analytic and statistical approaches are being applied to the complex data set to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways.

The Vietnam-Australia-US military study of drug resistance patterns in Central Vietnam was closed in Jan 2017 due to a lower than expected malaria burden. Preliminary data supports previous findings, reported in FY16, that there is no resistance for 1st choice malaria drug treatments. Additionally, a review of Vietnam malaria burden, control measures and environmental factors was initiated; the preliminary findings suggest increased average daily temperature was a primary factor of decreased malaria rates. Recruitment for the cross-sectional study in Gai Lia Province (on the border with Cambodia) started in Dec 2016 and was completed in Feb 2017. Sample and data analysis are ongoing, however, preliminary results from the >3,000 participants indicate the rate of patients without symptoms, but still carrying malaria parasite, was >1.25% in this study population, representing a silent malaria transmission risk in this forested, border region on the Cambodia-Vietnam border. The study of Vietnamese workers returning from Africa was initiated in Q2 FY17 with concurrent records review was stated for malaria patients recently returned from Africa presenting for care at two referral medical facilities in Ha Noi in 2014-2016. Preliminary results were accepted for presentation at the Joint International Tropical Medicine Meeting in Bangkok, Thailand from 06-08 Dec 2017. These data suggest delayed malaria clearance in patients returning from Africa was likely due to delayed medical treatment and not from malaria drug resistance.

FY 2018 Plans:

FY18 funding will support the continuation of the observational study at the Takeo Provincial Hospital in Cambodia and Komfo Anoke Teaching Hospital in Ghana, the sophisticated analytic and statistical approaches leading to development of the diagnostic and prognostic biomarker panels, and verification of the initial findings.

FY18 funding will also support the start of 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 2019 Plans:

FY19 funding will continue the support of the observational study at the Takeo Provincial Hospital in Cambodia and Komfo Anoke Teaching Hospital in Ghanna. It will also 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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
combined with prognostic markers for sepsis and common pathogenic pathway data to achieve improved patient outcomes. The project will come to an end in FY18/19, therefore, no funding is budgeted in the years following. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** The project will come to an end in FY18/19, therefore, no funding is budgeted in the years following.			
Accomplishments/Planned Programs Subtotals	1.079	1.238	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	10.245	3.471	5.327	5.523	-	5.523	5.633	5.745	5.859	5.976	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 2017	FY 2018	FY 2019
Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)	3.471	5.327	5.523
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 2018 Plans: Introduce early prevention, diagnosis, treatment, and evidence-based training through curriculum modification within U.S. Air Force basic training. Mitigating Heat Stress During Hot Weather Training and Operations In USAF Special Tactics Airmen. 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. Advance understanding of musculoskeletal injury in operational environment and assess new technologies for diagnosis and treatment.			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Mature a comprehensive program working to define and mitigate the extreme physiological and physical demands of higher altitudes to include decompression sickness and hypoxia. Continue work to demonstrate exposure to non-hypoxic hypobaria induces subcortical white matter injury by MRI. Further evaluation in modeling hypobaria-related white matter damage for detection of the biological / neuropathological indicators. Advance understanding of training for the operational environment as it pertains to new accessions, medical readiness, injury reduction, and retention. Complete studies assessing and validating vision standards for high risk and high demand career fields. Continue to understand the operational environment as it pertains to vision screening, evaluation and medical readiness. Further research in cognitive performance and mental resiliency by identifying occupational stressors and indicators to recovery. Converge medical research disciplines by implementing the Optimization of AF Human Capital Plan focused on medical readiness to support airman mission alignment. ***FY 2019 Plans:*** Continue implementation of the Optimization of AF Human Capital Research Plan focused on medical readiness to support airman mission alignment. Advance understanding of appropriate selection pertaining to new accessions, job placement, injury reduction and retention. Continue assessment and validation of standards across research lines in the areas vision, psychological, and physical physiological for high risk and high demand airman career fields. Develop model to assess and validate return of investment on embedded medics. Work to characterize at risk mission sets and operator/aircrew needs to optimize performance in high altitude environment to inform operational changes and determine safe altitudes for long-term exposures. Advance understanding of neuroprotection and/or neurotreatment therapies designed to mitigate hyperoxemic brain injury/effects. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	3.471	5.327	5.523

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 2019 Defense Health Agency		Date: February 2018
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)*

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
284C: *Core Human Performance R&D - Clinical Translational Focus (AF)*	1.003	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

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

B. Accomplishments/Planned Programs ($ in Millions)

N/A

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

SEE PROJECT CODE 284B PROGRAM FUNDING SUMMARY FOR PROJECT CODE 284C 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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
284D: *Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)*	1.002	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

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

B. Accomplishments/Planned Programs ($ in Millions)

N/A

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	16.914	6.194	2.699	4.702	-	4.702	5.514	5.624	5.736	5.851	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 2017	FY 2018	FY 2019
Title: Operational Medicine Research & Development (Air Force)	6.194	2.699	4.702
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 2018 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. Initiate research to enhance accession health and minimize/prevent training injury patterns. Utilize patient genomic information to individualize population health services. Continue regenerative/reconstructive research to validate technologies for surgical reconstruction of service members with previously non-reconstructable injuries. Expand composite tissue transfer to replantation of traumatic amputations and to advanced reconstruction with composite tissue allotransplantation. Provide guidance on the clinical impact of the new cell-based therapies as applied to improvements in fat grafting for warfighters requiring IED and burn wound reconstruction, and beneficiaries with other traumatic injuries. Evaluate silica encapsulated monomers for self-healing dental materials. Characterize Type 2 Diabetes prevention and care in the MHS. Assess proneuroregenerative therapies and collateral sensory reinnervation in peripheral nerve injuries. Evaluate triggable release, reloadable, smart hydrogels			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
for graft targeted immunotherapy in reconstructive transplantation. Examine diabetes self-management education via telemedicine in the USAF. ***FY 2019 Plans:*** Provide guidance on the clinical impact of the new cell-based therapies as applied to improvements in fat grafting for warfighters requiring IED and burn wound reconstruction, and beneficiaries with other traumatic injuries. Evaluate silica encapsulated monomers for self-healing dental materials. Characterize Type 2 Diabetes prevention and care in the MHS. Assess proneuroregenerative therapies and collateral sensory reinnervation in peripheral nerve injuries. Evaluate triggable release, reloadable, smart hydrogels for graft targeted immunotherapy in reconstructive transplantation. Examine diabetes self-management education via telemedicine in the USAF. Examine Eustachian Tube Dysfunction (ETD). Compare aeromedical care service delivery methods assessing for efficacy and efficiency in promoting beneficial outcomes in operators and their families. Continue research program to identify biomarkers of traumatic brain injury in warfighters using minimally invasive sample collection methods to improve aeromedical patient care. Develop autonomously designed DNA-based therapeutic interventions against emergent infectious diseases. Evaluate integrated operational medicine approach to characterize individualized aeromedical care. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Increase reflects right-sizing the program funding to reflect the actual execution of the program.			
Accomplishments/Planned Programs Subtotals	6.194	2.699	4.702

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 2019 Defense Health Agency		Date: February 2018
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)*

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
285B: *Core Operational Medicine R&D - Clinical Translational Focus (AF)*	0.929	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)

N/A

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

SEE PROJECT CODE 285A PROGRAM FUNDING SUMMARY FOR PROJECT CODE 285B 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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
285C: *Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)*	0.928	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

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)

N/A

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

SEE PROJECT CODE 285A PROGRAM FUNDING SUMMARY FOR PROJECT CODE 285C 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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	46.948	9.192	9.504	9.725	-	9.725	9.919	10.118	10.319	10.525	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 2017	FY 2018	FY 2019
Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force)	9.192	9.504	9.725
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 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to detect and identify the USAF- and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need. ***FY 2018 Plans:*** 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. 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. 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 study to evaluate breath biomarkers as diagnostic for influenza A. Examine alternate tinnitus management techniques using blood-oxygen-level-dependent MRI with neurofeedback. Evaluate genetic markers for musculoskeletal injuries and ailments. Continue response to fighter aircraft physiological events with R&D analysis of pilot breath and air cabin environment. Continue development and characterization of air quality sensing packages for aerospace environment and air supplies to determine health hazards and implement mitigations. Continue contaminant and exposure characterization. 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. Develop nanoparticle sensing prototype for infectious disease threat identification and surveillance. 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 new and innovative technologies to detect and assess hazardous chemical, biological, and physical agents relevant to AF deployment and garrison			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
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. 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. 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 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 study to evaluate breath biomarkers as diagnostic for influenza A. Examine alternate tinnitus management techniques using blood-oxygen-level-dependent MRI with neurofeedback. Evaluate genetic markers for musculoskeletal injuries and ailments. Develop and validate devices or methods that are extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Perform comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed. Develop capabilities for remote sensing of environmental hazards. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference. Perform assessment of subtle cognitive and respiratory effects of low-level exposures from low-level exposures in the challenging environments associated with AI operations. Initiate development of automated algorithms that incorporate environmental sensor and risk assessment to determine appropriate mitigation actions in real time as hazards are presented in-flight and in ground operations. Continue to study the role of the gut microbiome relevance to deployed airmen health and performance. Continue early detection, real time prediction of bioenvironmental impact, disease outbreak and intervention, data analytics and information sharing. Continue development and demonstration of the rapid transition of analytics tools that convert a multitude of health related data sources into actionable information based on operational context. Develop a communications platform that can collected exposure and health care data from multiple sources and transmit that data in a compressed format.			
FY 2019 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Develop Force and Individual Comprehensive Health Protection System (FInCH) that knows an individual health threat environment and assesses, documents, and informs actions on a real-time basis. 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 study to evaluate breath biomarkers as diagnostic for influenza A. Examine alternate tinnitus management techniques using blood-oxygen-level-dependent MRI with neurofeedback. Evaluate genetic markers for musculoskeletal injuries and ailments. 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 early detection, real time prediction of bioenvironmental impact, disease outbreak and intervention, data analytics and information sharing. Continue development and demonstration of the rapid transition of analytics tools that convert a multitude of health related data sources into actionable information based on operational context. Develop a communications platform that can collected exposure and health care data from multiple sources and transmit that data in a compressed format. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	9.192	9.504	9.725

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 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 2019 Defense Health Agency		Date: February 2018
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)*

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
307C: *Core Force Health Protection R&D - Clinical Translational Focus (AF)*	0.545	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

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)

N/A

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 2019 Defense Health Agency		Date: February 2018
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)*

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
307D: *Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)*	0.400	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

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)

N/A

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	13.340	2.206	4.554	4.645	-	4.645	4.737	4.833	4.929	5.028	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 2017	FY 2018	FY 2019
Title: Expeditionary Medicine Research & Development (Air Force)	2.206	4.554	4.645
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 2018 Plans:*** Investigate lifesaving hemorrhage control products that can be introduced to the field of combat casualty care as lifesaving interventions. Determine the efficacy of advanced hemorrhage control technologies in models of uncontrolled hemorrhage. Evaluate prehospital and en route analgesic use in traumatically injured patients to decrease post-treatment morbidity and mortality. 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 Members with vascular injury to address late repair success and functional outcomes. Investigate the near and long-term microvascular damage on normal intimal tissue caused by thoracic			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
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. Evaluate the current capability gap of emergency preservation and resuscitation for patient transport to higher echelons of care. Perform Selective Aortic Arch Perfusion (SAAP) to treat both uncontrolled hemorrhage and to induce suspended animation by profound hypothermia. Determine optimal infusion solutions and delivery paradigm for inducing hypothermic arrest in a model of noncompressible torso hemorrhage with a SAAP catheter. Determine the ability to improve the practicality of using SAAP by testing new and advanced SAAP mechanical components, pumps, catheters, and oxygenators. 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. Continuation of 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 and non-invasively estimate current and future intracranial pressure and neurologic status. 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. Investigate novel targeted intravascular therapeutics which provides hemorrhage control. Pilot the use of ECMO and developing closed loop control. Continue to investigate small molecules which modulate the immune system and the response to trauma. Investigate lifesaving hemorrhage control products that can be introduced to the field of combat casualty care as lifesaving interventions. Determine the efficacy of advanced hemorrhage control technologies in models of uncontrolled hemorrhage. Evaluate prehospital and en route analgesic use in traumatically injured patients to decrease post-treatment morbidity and mortality. 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 Members with vascular injury to address late repair success and functional outcomes. 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			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
for use in pre-clinical and translational research pertaining to acute lung injury and adjunct therapies for “suspended animation” technologies. Evaluate the current capability gap of emergency preservation and resuscitation for patient transport to higher echelons of care. Perform Selective Aortic Arch Perfusion (SAAP) to treat both uncontrolled hemorrhage and to induce suspended animation by profound hypothermia. Determine optimal infusion solutions and delivery paradigm for inducing hypothermic arrest in a model of noncompressible torso hemorrhage with a SAAP catheter. Determine the ability to improve the practicality of using SAAP by testing new and advanced SAAP mechanical components, pumps, catheters, and oxygenators.			
FY 2019 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 cryopreserved blood products, rhabdomyolysis, neuroprotection, and ischemia-reperfusion injury. Transition multi-channel negative pressure wound treatment system to advanced development. 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. Evaluate Cell-free DNA as an Injury Severity Marker in traumatic brain injury and acute lung injury. Assess the use of the Abdominal Aortic and Junctional Tourniquet (AAJT) during CPR after traumatic cardiac arrest and as a Stop-Gap for Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) insertion. Determine the comparative benefit of prolonged exposure to an FDA approved complement inhibitor in a pre-/early hospital swine model of polytrauma. Evaluate sustained release, stimuli responsive, smart hydrogels for prevention, modulation and management of acute pain. Continue characterization of early biomarkers in a swine model of polytrauma. Optimize REBOA and ECLS to treat combat relevant trauma at ground level and high altitude. Compare utility of standard left lateral thoracotomy vs. modified bilateral “clam shell” thoracotomy by emergency physicians. Evaluate hydroxocobalamin for neuroprotection and survival in a hemorrhagic swine model of traumatic brain ischemia. Evaluation of Stem-Cell Based Therapeutics for protection from Acute Lung Injury and Acute Respiratory Distress Syndrome. Assessment of a pharmacologic blockade of Interleukin-1 (IL-1) signaling to promote systemic and cerebral protection after hemorrhagic shock and traumatic brain injury. Evaluation of the mitigation of burn injury severity and infection rates using a novel dressing that targets multiple burn-related pathologies. Evaluation of prolonged field care resuscitation guided by blood pressure versus cerebral perfusion in a swine model of hemorrhage and traumatic brain injury. Evaluate the efficacy of prophylactically reducing post-trauma sepsis risks with TLR8 agonists. Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Continuation of 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 and non-invasively estimate current and future intracranial pressure and neurologic status. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Investigate lifesaving hemorrhage control product that can			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
be introduced to the field of combat casualty care as lifesaving interventions. Investigate novel targeted intravascular therapeutics which provides hemorrhage control. Pilot the use of ECMO and developing closed loop control. Continue to investigate small molecules which modulate the immune system and the response to trauma. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	2.206	4.554	4.645

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
308C: *Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)*	1.503	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

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)

N/A

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

SEE PROJECT CODE 308B PROGRAM FUNDING SUMMARY FOR PROJECT CODE 308C 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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
308D: *Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)*	1.502	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

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)

N/A

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

SEE PROJECT CODE 308B PROGRAM FUNDING SUMMARY FOR PROJECT CODE 308D 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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
309A: *Regenerative Medicine (USUHS)*	31.071	9.520	7.373	8.327	-	8.327	10.209	10.413	10.621	10.833	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 2017	FY 2018	FY 2019
Title: Regenerative Medicine (USUHS)	9.520	7.373	8.327

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

FY 2018 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 Clinical Trials Unit and start-up research of one new USU faculty member to develop clinical research capability; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY18 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host internal CNRM data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research;(11) Support fellowship program to facilitate neuroscience and regenerative medicine research capabilities at DoD sites in NCA; (12) Participate on the Traumatic Brain Injury (TBI) Research Synergy Board (RSB) and contribute to the TBI “Unity of Effort” to strategically strengthen and accelerate TBI research on “America’s Health Campus;” (13) Utilize Biospecimen Bank of blood specimens linked to MRI and clinical assessment data in longitudinal studies of TBI patients and relevant comparison cohorts; (14) Brain Tissue Repository of brains donated from military TBI patients, including state-of-the-art neuropathological analysis of blast cases and relevant comparison cohorts;

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
(15) Deployment of multi-modal forms of advanced imaging technology for diagnosis of TBI, with and without co-morbid PTSD, including MRI-PET, hyperacute MRI, and novel diffusion imaging techniques such as Mean Apparent Propagator; (16) Creation of Work flow pipeline for accurate and efficient analysis of neuroimaging data relevant to TBI, including quantitative analysis of microhemorrhages, traumatic meningeal injury, and white matter abnormalities; (17) Utilize multiple animal models involving multiple species for improved analysis of acute and chronic effects of TBI relevant to the warfighter, including blast exposure, repetitive injury, and stress conditions.			
FY 2019 Plans: FY19 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)Develop Clinical Trials Unit and expand clinical research capability to increase the number of interventional trials ; (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 FY19 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host CNRM retreat and internal data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research;(11) Support fellowship program to facilitate neuroscience and regenerative medicine research capabilities at DoD sites in NCA; (12) Participate on the Traumatic Brain Injury (TBI) Research Synergy Board (RSB) and contribute to the TBI “Unity of Effort” to strategically strengthen and accelerate TBI research on “America’s Health Campus;” (13) Utilize Biospecimen Bank of blood specimens linked to MRI and clinical assessment data in longitudinal studies of TBI patients and relevant comparison cohorts; (14) Brain Tissue Repository of brains donated from military TBI patients, including state-of-the-art neuropathological analysis of blast cases and relevant comparison cohorts; (15) Deployment of multi-modal forms of advanced imaging technology for diagnosis of TBI, with and without co-morbid PTSD, including MRI-PET, hyperacute MRI, and novel diffusion imaging techniques such as Mean Apparent Propagator; (16) Creation of Work flow pipeline for accurate and efficient analysis of neuroimaging data relevant to TBI, including quantitative analysis of microhemorrhages, traumatic meningeal injury, and white matter abnormalities; (17) Utilize multiple animal models involving multiple species for improved analysis of acute and chronic effects of TBI relevant to the warfighter, including blast exposure, repetitive injury, and stress conditions.			
FY 2018 to FY 2019 Increase/Decrease Statement:			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	9.520	7.373	8.327

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
• BA-1, 0806721HP: *Uniformed Services University of the Health Sciences*	9.272	9.458	9.647	-	9.647	9.840	10.036	10.236	-	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 FY16 through FY19, 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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
373A: *GDF - Medical Technology Development*	508.755	135.552	126.790	128.578	-	128.578	130.412	139.561	143.781	146.566	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: GDF – Medical Technology Development	135.552	126.790	128.578
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 2018 Plans: Medical simulation and information sciences technology maturation is focusing on developing and integrating pharmacodynamics and pharmacokinetics algorithms into an open source physiology research engine that is used to support a repository that contains simulated pharmaceuticals and other resuscitative treatments that are the most relevant to point of injury and en route care training. It is incorporating the side effects of the drugs and drug/drug interactions to elicit how to deal with additional acute reactions. This repository is designed to improve medical simulation and training. Research also is also focusing on assessment system tools with emphasis on combat casualty care training. Synthetic materials are being optimized for part-task mannequins, full body mannequins, or peripherals that could be used on the Advanced Modular Manikin in order to better represent tissues under different environments.			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Military infectious diseases research continues to support the inter-service efforts between DoD clinical and research and development groups to develop novel and innovative therapeutics and delivery technologies for combat wound infections. Ongoing multi-year studies addressing critical research focus areas in wound infections, such as improved treatment options for infections with multi-drug resistant organisms, are also being supported. These efforts are in alignment with the National Action Plan for Combating Antibiotic-Resistant Bacteria. Results of studies to develop antibacterial and clinical practice guidelines for better wound infection management are being evaluated in order to down-select promising solutions. Efforts aimed at partnering with other entities to rapidly accelerate promising, innovative drug and vaccine solutions to combat emerging infectious diseases (e.g., Chikungunya, MERS, Zika) are ongoing. Military operational medicine: Researchers continue to collect blast exposure data to validate whole body models of blast injury exposure in the training environment. Refining and improving predictive auditory injury models in order to update acoustic injury standards for health hazard assessment. Developing tools to optimize return to duty after lower extremity (foot and ankle) injury, and head supported mass acute injury predictive models for mounted and dismounted environments. Collecting data to improve multisensory cueing criteria for aircrew performance optimization in degraded visual environments. Evaluating longitudinal data collected for dietary supplement use with correlation to usage patterns with associated negative and positive health effects. Providing guidance on the effects of healthy cooking for food choice behaviors, nutritional status, and psychological states in wounded Warriors and their families. Evaluating the physical demands associated with selection to historically male military occupations to develop gender-neutral Military Occupational Specialty assignment standards. Conducting research aimed at delivering assessment, prevention, and treatment interventions and tools that mitigate substance abuse, including prescription drug misuse and alcohol and other drug abuse. Developing interventions to prevent suicide behaviors and conduct clinical trials to test the efficacy of the interventions. Continuing efforts toward delivering resilience building/prevention programs focused on education, skills, and novel service delivery methods for Service member and Family resilience. Concluding several large scale intervention studies evaluating pharmacologic (drug action), psychotherapy, and augmented psychotherapy (virtual reality and/or pharmacologic cognitive enhancement) treatments for PTSD. Using newly built and existing large-scale PTSD datasets and state-of-the-art analytic methods to produce individualized treatment guidelines for PTSD as well as PTSD-related sleep disturbances. Validating candidate biomarkers of exposure to inhaled or ingested toxic substances and developing medical guidance for risk assessment of adverse health outcomes. Conducting research to provide validated metrics for optimized operational task performance in extreme environments. Validating novel methods for estimating thermal strain from non-invasive measures. Combat casualty care hemorrhage research is evaluating immune system modulating drugs to treat hemorrhagic shock with a focus on the time period of 4 to 72 hours post injury (relevant to prolonged field care). Research is continuing on the pathophysiological (functional changes associated with injury) impacts of using advanced hemorrhage (bleeding) control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. In animal studies, oxygen delivery solutions that can be infused to maintain survivability are being evaluated for potential use in severe casualties where blood			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
transfusion is not available. Neurotrauma research is focusing on the development of novel technologies to better assess, monitor and maintain the stability of more severely injured TBI casualties closer to point of injury and during prolonged field care. Precision medicine research is anticipated to improve the characterization of TBI, development of targeted therapies, devices, clinical guidelines, and assessment of the impact of pre-injury conditions and the environment to improve the care provided to TBI casualties. Neurotrauma research is investigating the impact of pre-injury conditions and the environment on Service member response to treatment and recovery following TBI. The program leverages data from Combat Operations to improve management of TBI by correlating injury events and medical records. Treatments for extremity trauma is continuing to develop specialized fracture stabilization techniques, address treatments for organ support and stabilization of craniomaxillofacial wounds. Pre-hospital Tactical Combat Casualty Care is developing enhanced surgical procedures and equipment. En Route Care research is continuing to develop the specifications of an integrated system to support safe patient care and hand-offs, and to develop expanded en route care interventions and treatment capabilities, to include non-invasive monitoring technologies. The military medical photonics program is developing light-based technologies and systems for combat casualty care and transition to advanced development. Particular emphasis is on creating a portable platform for photo-acoustic imaging, and demonstrating its application to detecting blood pooling in the abdomen and oxygen content in the pulmonary artery. Photochemical cross-linking (the use of light to create new molecular bonds) to strengthen veins for grafting to arteries in wounded warrior surgery is being evaluated, as are the post-surgical benefits of photochemical bonding (the use of light to create new molecular bonds) in reducing scarring and adhesions. The general theme of the medical photonics program is developing miniaturized sensors and actuators which can be inserted or implanted for important new kinds of diagnostic and therapeutic benefit. Radiation health effects research continues to evaluate therapeutic candidates and radioprotectants for acute radiation exposure, and develop data to support preparation of a technical data package for investigational new drug applications. Research is developing data to support qualification of models for use in FDA approved trials. Objectives include demonstrating improved survivability following high doses of radiation exposure with treatment at 24 hours and less after exposure. Clinical and rehabilitative medicine efforts are focused on early human trials of promising products, evaluating preclinical safety of promising treatments, and testing FDA-licensed products in the areas of neuromusculoskeletal injury, pain management, and regenerative medicine. Supporting clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation outcomes after Service-related injuries. Evaluating novel therapeutics and devices for pain management. Assessing chronic pain risk factors. Assessing preclinical and early clinical safety and efficacy of technologies designed to alter or regulate immune functions, skin substitutes to treat burn injury, treatments for volumetric muscle loss, treatments for segmental bone defects, and strategies for stabilization or regeneration of neuromuscular junctions for nerve injury.			
FY 2019 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Medical simulation and information sciences technology maturation will continue to focus on developing and integrating pharmacodynamics and pharmacokinetics algorithms into an open source physiology research engine that is used to support a repository that contains simulated pharmaceuticals and other resuscitative treatments that are the most relevant to point of injury and en route care training. It will incorporate the side effects of the drugs and drug/drug interactions to elicit how to deal with additional acute reactions. This repository is designed to improve medical simulation and training. Research will also continue to focus on assessment system tools with emphasis on combat casualty care training. Will continue to optimize synthetic materials used in part-task mannequins, full body mannequins, or peripherals that could be used on the Advanced Modular Manikin in order to better represent tissues under different environments. Military infectious diseases research will continue supporting the inter-service efforts between DoD clinical and research and development groups to develop novel and innovative therapeutics and delivery technologies for combat wound infections. On-going multi-year studies addressing critical research focus areas in wound infections, such as improved treatment options for infections with multi-drug resistant organisms, will continue to be supported. These efforts will be in alignment with the National Action Plan for Combating Antibiotic-Resistant Bacteria. Results of studies to develop antibacterial agents and clinical practice guidelines for better wound infection management will continue to be evaluated for down-selection. Will continue efforts aimed at partnering with other entities to rapidly accelerate promising, innovative drug and vaccine solutions to combat emerging infectious diseases (e.g., Chikungunya, MERS, Zika). Military operational medicine: Researchers will continue to collect blast exposure data to validate whole body models of blast injury exposure in the training environment. Will continue research to refine and improve predictive auditory injury models in order to update acoustic injury standards for health hazard assessment. Will continue to develop tools to optimize return to duty after lower extremity (foot and ankle) injury, and head supported mass acute injury predictive models for mounted and dismounted environments. Will continue to collect data to improve multisensory cueing criteria for aircrew performance optimization in degraded visual environments. Will continue to evaluate longitudinal data collected for dietary supplement use with correlation to usage patterns with associated negative and positive health effects. Will continue to provide guidance on the effects of healthy cooking for food choice behaviors, nutritional status, and psychological states in Wounded Warriors and their families. Will continue studies evaluating the physical demands associated with selection to historically male military occupations to develop gender-neutral Military Occupational Specialty assignment standards. Will continue research aimed at delivering assessment, prevention, and treatment interventions and tools that mitigate substance abuse, including prescription drug misuse and alcohol and other drug abuse. Will continue efforts toward delivery of interventions to prevent suicide behaviors and conduct clinical trials to test the efficacy of the interventions. Will perform studies aimed at delivering resilience building/prevention programs focused on education, skills, and novel service delivery methods for Service member and Family resilience. Will use newly built and existing large-scale PTSD datasets and state-of-the-art analytic methods to produce individualized treatment guidelines for PTSD as well as PTSD-related sleep disturbances. Will continue to validate candidate biomarkers of exposure to inhaled or ingested toxic			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
substances and develop medical guidance for risk assessment of adverse health outcomes. Will continue to conduct research to provide validated metrics for optimized operational task performance in extreme environments. Will continue to validate novel methods for estimating thermal strain from non-invasive measures. Combat casualty care hemorrhage research will continue to evaluate immune system modulating drugs to treat hemorrhagic shock with a focus on the time period 4 to 72 hours post injury (relevant to prolonged field care). In addition, work will continue on the pathophysiological (functional changes associated with injury) impacts of using advanced hemorrhage (bleeding) control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Will continue animal studies to evaluate oxygen delivery solutions that can be infused to maintain survivability for potential use in severe casualties where blood transfusion is not available. Neurotrauma research will continue to focus on the development of novel technologies to better assess, monitor and maintain the stability of more severely injured TBI casualties closer to point of injury and during prolonged field care. Precision medicine research will continue to improve the characterization of TBI, develop targeted therapies, devices, clinical guidelines, the impact of pre-injury conditions and the environment to improve the care provided to TBI casualties. Furthermore, neurotrauma research will continue to investigate the impact of pre-injury conditions and the environment on Service member response to treatment and recovery following TBI. The program will also leverage data from Combat Operations to improve management of TBI by correlating injury events and medical records. Treatments for extremity trauma will continue to develop specialized fracture stabilization techniques, address treatments for organ support and stabilization of craniomaxillofacial wounds. Pre-hospital Tactical Combat Casualty Care will develop enhanced surgical procedures and equipment. En Route Care research will continue to develop the specifications of an integrated system to support safe patient care and hand-offs, and the development of expanded En Route care interventions and treatment capabilities, to include non-invasive monitoring technologies. The military medical photonics program will continue to develop light-based technologies and systems for combat casualty care and transition to advanced development. Particular emphasis will continue to 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 continue to be evaluated, as will the post-surgical benefits of photochemical bonding (the use of light to create new molecular bonds) in reducing scarring and adhesions. The general theme of the medical photonics program will be to develop miniaturized sensors and actuators which can be inserted or implanted for important new kinds of diagnostic and therapeutic benefit. Radiation health effects research will continue to evaluate therapeutic candidates and radioprotectants for acute radiation exposure, and develop data to support preparation of a technical data package for investigational new drug applications. Research will develop data to support qualification of models for use in FDA approved trials. Objectives will include demonstrating improved survivability following high doses of radiation exposure with treatment at 24 hours and less after exposure.			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Clinical and rehabilitative medicine will conduct early human trials of promising products, evaluate preclinical safety of promising treatments, and test FDA-licensed products in the areas of neuromusculoskeletal injury, pain management, and regenerative medicine. Will support clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation outcomes after Service-related injuries. Will assess chronic pain risk factors and evaluate novel therapeutics and devices for pain management. Will assess preclinical and early clinical safety and efficacy of technologies designed to alter or regulate immune functions, skin substitutes to treat burn injury, treatments for volumetric muscle loss, treatments for segmental bone defects, and strategies for stabilization or regeneration of neuromuscular junctions for nerve injury. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Includes $8.0 million realignment for the WRAIR research project.			
Accomplishments/Planned Programs Subtotals	135.552	126.790	128.578

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
378A: *CoE-Breast Cancer Center of Excellence (Army)*	39.699	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 Breast Cancer Center of Excellence provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. This approach integrates prevention, screening, diagnosis, treatment and continuing care, incorporation of advances in risk reduction, biomedical informatics, tissue banking and translational research. The project is based on a discovery science paradigm, leveraging high-throughput molecular biology technology and our unique clinically well-characterized tissue repository with advances in biomedical informatics leading to hypothesis-generating discoveries that are then tested in hypothesis-driven experiments. The objective of this research is to reduce the incidence, morbidity (illness), and mortality (death) of breast diseases and breast cancer among all military beneficiaries.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: Breast Cancer Center of Excellence	0.000	0.000	0.000
Description: Provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. ***FY 2018 Plans:*** No funding programmed. ***FY 2019 Plans:*** No funding programmed. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** N/A			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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)*

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
378B: *CoE-Breast Cancer Center of Excellence (USU)*	0.000	10.552	9.088	10.280	-	10.280	10.475	10.685	10.898	11.116	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 2017	FY 2018	FY 2019
Title: Breast Cancer Center of Excellence	10.552	9.088	10.280
Description: Breast Cancer CoE provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.			
FY 2018 Plans: The Breast Cancer CoE will continue to enhance active duty female readiness through study of the increased breast cancer incidence rate in the active duty force by the process of banking biospecimens in the DoD's biorepository, using the repository for intramural/extramural collaborations and secondary usage research. Will continue to develop and improve quality assurance programs and standard operating procedures for the Tissue Bank including conducting biospecimen science research. Will continue to conduct integrative profiling research, for protein-expression based, clinically relevant breast cancer stratification on active case IHC assays of a panel of 20 ImmunoHistoChemical (IHA) biomarker and IHC assays of a panel of 27 biomarkers named Connectivity Map EnHigh Density TMA analysis of biomarkers associated with the development of endocrine resistance. Will conduct breast cancer studies focused on two special patient groups bearing poor outcomes, who are enriched in the military active-duty military population: young women, and African American women. Will conduct breast cancer heterogeneity studies, including cellular heterogeneity of tumor development environment and lineage heterogeneity within one physical cancer tumor. Will conduct studies on mechanistic understanding of breast cancer development from other perspectives, including genetic dispositions, exposure to environmental risks, access to healthcare, and impact of certain life style factors as well as comorbidities. Will conduct breast cancer drug target studies focusing on the triple negative and HER2 subtypes, using 2D and 3D tissue culturing systems and human breast cancer tissues, respectively. Will further develop the informatics infrastructure system to support the evolving needs of Breast Cancer-COE research. Will conduct integrative biomedical data analysis and develop a Breast Cancer Knowledge Base to aid clinical decision-making.			
FY 2019 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
The Breast Cancer CoE will identify and consent patients (to include patients at high risk for development of breast cancer) annually to the MCC ORIEN research study, with special focus on active duty females as a Force Protection / Readiness sustainment issue to the DoD. Will continue to accrue patients annually to the "core" BC-COE protocols through consenting patients in the main BC-COE clinical sites, with the main site being the Breast Center at the Murtha Cancer Center of Walter Reed NMMC, the military's largest and only NAPBC (National Accreditation Program for Breast Centers) approved breast center in the entire DoD MHS. Will acquire through consented protocol acquisitions, over 5,000 specimens annually (neo-plastic and non-neoplastic breast tissues and tumors, lymph nodes, metastatic deposits, blood and its components, bone marrow) on patients with all types of breast diseases and cancer. Will bank these biospecimens in the BC-COE Biorepository as the substrate for all molecular analyses carried out in BC-COE labs, as outlined in the BC-COE Core Protocols. Will utilize the repository as the basis for intramural and extramural collaborations for secondary usage research. Will continue to conduct integrative profiling research, for protein-expression based, clinically relevant breast cancer stratification on active case IHC assays of a panel of 20 ImmunoHistoChemical (IHA) biomarker and IHC assays of a panel of 27 biomarkers named Connectivity Map EnHigh Density TMA analysis of biomarkers associated with the development of endocrine resistance. Will continue to focus breast cancer studies on two special patients groups bearing poor outcomes, who are enriched in the military active-duty military population: young women, and African American women. Will continue to conduct breast cancer heterogeneity studies, including cellular heterogeneity of tumor development environment and lineage heterogeneity within one physical cancer tumor. Focus areas will be (Breast Cancer Immunome, identification of molecular factors in tumor epithelium and stroma contributing to tumor etiology and breast cancer tumor heterogeneity study through Whole Genome Sequencing. Will conduct studies on mechanistic understanding of breast cancer development from other perspectives, including genetic dispositions, exposure to environmental risks, access to healthcare, and impact of certain life style factors as well as comorbidities. Will continue to conduct breast cancer drug target studies focusing on the triple negative and HER2 subtypes, using 2D and 3D tissue culturing systems and human breast cancer tissues, respectively. Will further develop the informatics infrastructure system to support the evolving needs of Breast Cancer-COE research which will include developing the replacement system for the Clinical Laboratory Workflow System that was implemented years ago, develop and improve data QA programs and SOPs and improve the Data Warehouse for Translational Research by integrating data generated by internal scientists, through collaborations, and those available in the public as needed to facilitate integrative data analysis. The Breast Cancer COE will also continue its Collaborative Translational Research Program. CBCP will fund breast specific collaborative research that addresses problems with translational potential with a focus on environmental factors and the tumor microenvironment. The translational research program will consist of numerous investigators pursuing basic research on breast specific cancer etiology and biology or translational cancer research studies. CBCP will seek to establish support of novel intramural research that has the potential to improve breast cancer outcomes. The goal is to promote collaborative translational research efforts among translational science laboratories at the Clinical Breast Care Project, WRNNMC-MCC, WRI and NCI.			
FY 2018 to FY 2019 Increase/Decrease Statement:			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
N/A			
Accomplishments/Planned Programs Subtotals	10.552	9.088	10.280

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	34.939	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 Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and biologic therapeutics for the management of gynecological disease. The objective of this research is to reduce the incidence, morbidity (illness), and mortality (death) of gynecological diseases among all military beneficiaries.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: Gynecological Cancer Center of Excellence (Army) ***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 2018 Plans:*** No funding programmed. ***FY 2019 Plans:*** No funding programmed. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** N/A	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 medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, incorporation into training curriculum throughout the Military Health System, and other applicable means.

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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)*

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 2019 Defense Health Agency			Date: February 2018
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 379B / *CoE-Gynecological Cancer Center of Excellence (USU)*	

COST ($ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
379B: *CoE-Gynecological Cancer Center of Excellence (USU)*	0.000	9.226	7.943	8.987	-	8.987	9.158	9.341	9.528	9.719	Continuing	Continuing

Note

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: Gynecological Cancer Center of Excellence	9.226	7.943	8.987
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 2018 Plans: The FY2018 program will continue to identify molecular alterations in gynecologic cancers and develop novel strategies for prevention, early detection, and precision treatment of these diseases. This will be accomplished by investigating ovarian, uterine and cervical carcinogenesis (the initiation, progression, and metastatic spread of cancer) and drug resistance in pre-clinical and clinical biospecimens. We will develop and deploy clinical biomarkers and assays for gynecologic malignancies throughout the spectrum of care and improve clinical care and outcome through evaluation of novel therapeutics, prevention strategies, assessments and interventions in gynecological oncology using pre-clinical studies and clinical trials. We will continue to collaborate in investigations of racial and ethnic disparities, risk, outcome, natural history, lifestyle, staging and treatment in cancer including gynecologic malignancies. Military and civilian biobanks, registries, core facilities, training programs, and multidisciplinary investigations will be used to advance applied proteogenomics and organizational learning, and to ensure			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 379B / *CoE-Gynecological Cancer Center of Excellence (USU)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
readiness, cost containment and improvements in clinical care and outcomes in gynecologic oncology. An overarching goal during this period is to advance patient awareness, education, support and survivorship to improve quality of life, patient experience and mitigate effects. These efforts enhance the experience of care, ensure readiness of the fighting force, and improve beneficiary health adding value while decreasing cost for the Department of Defense. ***FY 2019 Plans:*** The FY2019 program will continue to develop novel strategies for prevention, early detection, and precision treatment of gynecologic cancers by identifying molecular alterations in these diseases. We will deeply interrogate ovarian and uterine cancer looking at the complex interplay of tumor cells and the surrounding stroma (or physiologic niche) that supports carcinogenesis (the initiation, progression, and metastatic spread of cancer) as well as the molecular landscape of primary versus metastatic disease. These investigations will facilitate development of clinical biomarkers and assays for gynecologic malignancies throughout the spectrum of care and improve early diagnosis and clinical care. Beyond the above studies, we will continue to build on studies examining molecular determinants of recurrent versus non-recurrent disease and how distribution or disease and post-surgical tumor residual influences outcome. Deep proteogenomic analyses will extend current state of the art to reveal clinically actionable data to improve readiness by earlier detection and prevention of disease in the active duty force and decrease the economic burden of disease in the MHS which his typically diagnosed at late stages and treated without great specificity. We will expand collaborations in investigations of racial and ethnic disparities, risk, outcome, natural history, lifestyle, staging and treatment in cancer including gynecologic malignancies. Under the broad umbrella of outreach and patient reported outcomes research, an overarching goal during this period is to advance patient awareness, education, support and survivorship to improve quality of life, patient experience and mitigate effects. These efforts enhance the experience of care, ensure readiness of the fighting force, and improve beneficiary health adding value while decreasing cost for the Department of Defense. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** N/A			
Accomplishments/Planned Programs Subtotals	9.226	7.943	8.987

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 into training curriculum throughout the Military Health System, and other applicable means.

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 379B / *CoE-Gynecological Cancer Center of Excellence (USU)*

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	15.032	3.051	2.697	0.000	-	0.000	0.000	0.000	0.000	0.000	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 2017	FY 2018	FY 2019
Title: Integrative Cardiac Health Center of Excellence (Army)	3.051	2.697	0.000
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 2018 Plans: The Integrative Cardiac Health Center of Excellence (ICHP) will influence clinical practice guidelines by developing clinical decision support tools and new models for cardiovascular and overall health; will conduct research studies to improve the health of the Active Duty force by investigating the effectiveness of personalized (gender specific) lifestyle change interventions specifically designed for the military and the effects of these interventions on preclinical atherosclerosis (plaque in arteries). ICHP will continue recruitment in the study to investigate the effects of lifestyle intervention to improve cardiovascular health and reduce cardiovascular disease risk in AD Service members and beneficiaries especially targeting the population that are presumably fit but still vulnerable for sudden cardiac death and heart attacks. ICHP will initiate a precision medicine effort that will explore novel biomolecular markers and tests as indicators for early (preclinical) cardiovascular disease risk assessment, and discover and characterize new clinical phenotypes, detect cardiovascular disease in early stages when it is more likely to be reversible. ICHP will collaborate with Walter Reed Bethesda Cardiovascular Service, the Mayo Clinic, Abbott Laboratories, and Integrative			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 381A / *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Systems Biology for these efforts. ICHP will use this information to tailor personalized health interventions and build resiliency in the military population before disease affects quality of life. ICHP will collaborate with the Department of Psychology within the Uniformed Services University of Health Sciences to evaluate the benefits of ICHP Cognitive Behavioral Therapy intervention to relieve insomnia. The Wounded Warriors project will explore cardiovascular risk in the amputee and injured Warfighter to include the collection of bio-samples for novel biomolecular markers designed to significantly advance the precision of risk detection to better tailor health interventions. ***FY 2019 Plans:*** No funding programmed. Beginning in FY19, the ICHP funding line is transferred from the Army to USUHS Project 381. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** No funding programmed. Beginning in FY19, the ICHP funding line is transferred from the Army to USUHS Project 381.			
Accomplishments/Planned Programs Subtotals	3.051	2.697	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, and training of residents and fellows in the Military Health System

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
382A: *CoE-Pain Center of Excellence (Army)*	6.436	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
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 2018 Plans:*** No funding programmed. ***FY 2019 Plans:*** No funding programmed. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** N/A			
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 2019 Defense Health Agency		Date: February 2018
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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
382B: *CoE-Pain Center of Excellence (USUHS)*	5.094	2.985	2.822	3.310	-	3.310	3.376	3.445	3.514	3.584	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 2017	FY 2018	FY 2019
Title: Pain Center of Excellence (USUHS)	2.985	2.822	3.310
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 2018 Plans: The DVCIPM will continue to focus on further building and streamlining the Pain Assessment Screening Tool and Outcomes Registry (PASTOR)and apply for grants for data analysis. DVCIPM will continue to focus on complementary and integrative pain management (CIPM) through clinical assimilation studies of modalities such as: battlefield acupuncture (BFA); yoga and massage; evaluation of novel analgesics; and interventional technologies for improved pain management. Pain education and policy development will continue to be a primary theme.			
FY 2019 Plans: The DVCIPM will continue to focus on further building and streamlining the Pain Assessment Screening Tool and Outcomes Registry (PASTOR) and apply for funding for data analysis. Continue to foster collaborative relationships and 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. DVCIPM will seek additional funding to sustain the Pain Education Program, as well as support the increasing requirements for the MHS DVCIPM's designation as a MHS CoE, and DVCIPM's recognized track record of effective facilitating collaborations across the Uniformed Services, VA, and Civilian Medicine has resulted in an ever-growing number of tasks.			
FY 2018 to FY 2019 Increase/Decrease Statement:			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	2.985	2.822	3.310

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	33.379	8.443	7.250	8.203	-	8.203	8.359	8.526	8.696	8.870	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: CoE-Prostate Cancer Center of Excellence (USUHS)	8.443	7.250	8.203
Description: The CPDR is at the forefront of "cutting-edge" clinical, basic science and epidemiologic research. The emphasis is on improving diagnosis, prognosis and treatment of prostate cancer involving new modalities such as MRI guided biopsy, gene-based biomarkers, and precision medicine strategies targeting causal gene alterations in prostate cancer. The CPDR multi-center database is a unique programmatic resource, enrolling over 27,500 DoD health care beneficiaries under suspicion for prostate cancer, with longitudinal follow up to 23 years. This database continues to highlight emerging issues in prostate cancer management such e.g., treatment outcomes, racial/ethnic differences, quality of life and discovery of novel molecular prognostic markers. In light of current issues related to overtreatment of early detected prostate cancers and poorly understood biology of prostate cancer, CPDR's long-term biospecimen banks, high-impact discoveries and collaborations are leading towards better diagnostic and prognostic molecular markers and therapeutic targets with promise in improving the management of the disease. The CPDR's health disparity research focus has uniquely benefited from studying a prostate cancer patient cohort, with a high representation of African American men, in an equal-access military health care system. Ground-breaking studies of the most validated prostate cancer gene, ERG, in over 1,500+ patients provide the first definitive information on prostate cancer biology underscoring racial/ethnic differences with potential to enhance personalized medicine. The CPDR's state-of-the-art research infrastructure and framework is providing education and training for over 100 next generation physicians, scientists, medical and graduate students within DoD medical institutions.			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
FY 2018 Plans: Precision Medicine Focus: • Refine and develop modalities for diagnosing and prognosing clinically significant cancers prostate cancers. Build on the molecular/clinico-pathologic prognostic signatures of MRI-ultrasound fusion image guided biopsy specimens. • Enhance the support for national cancer precision medicine initiatives e.g., Cancer Moonshot under the Murtha Cancer Center. Build on APOLLO projects initial experience on proteogenomics signatures. • Continue to leverage the large, longitudinal DoD cohort of racially diverse prostate cancer patients to develop and validate prediction models for disease progression, quality of life, and overall survival across the spectrum of cancer treatments, as well as identify factors that predict definitive treatment for patients initially managed on active surveillance. • Build on data that will lead to military-specific exposures in prostate cancer onset and progression assessing the role of predisposing conditions (e.g., environmental and genetic) to service members. • Deploy multi-center validation of the diagnostic and prognostic biomarker panels from integrated omics study addressing the limitations of currently used serum PSA diagnostic test (collaboration with Berg Pharma). Health Disparity Research: • Continue to leverage CPDR's lead towards identification of genes that will enhance diagnosis, prognosis and treatment of racially diverse prostate cancer patients in MHS: Develop synergy with USU, The American Genome Center to perform whole-genome and whole-transcriptome sequencing on a large CPDR cohort of African American and Caucasian American patients with defined clinical attributes (patients with aggressive disease progression versus indolent disease). • Lead the research delineating the comprehensive molecular taxonomy of under studied prostate cancer genomes (African American and Asians) towards enhancing diagnosis, prognosis and treatment broadly applicable to the US population. • Continue to enhance experimental models focusing on prostate cancer driver genes prevalent for innovating novel therapeutic strategies. • Enhance collaborations with NCI investigators on genetic predisposition for metastatic prostate cancer. Development of Molecular Diagnostic and Prognostic Tools: • Continue to enhance and leverage the unique DoD prostate cancer research resources integration of clinical, biospecimen and molecular databases through advanced informatics platforms to enhance development of diagnostic and prognostic tools. • Continue to enhance the prognostic utility of the CPDR-ERG monoclonal antibody in the context of ethnicity and co-morbidities. • Develop and validate gene-based broadly applicable diagnostic and prognostic biomarkers in multi-center setting, e.g., evaluation of CPDR gene panels in urine exosomes in clinical trial and collaboration with the Exosome Diagnostics Inc. • Expand the research on serum and tissue based omics-defined biomarkers (mass spectrometry-based, serum antigen- and autoantibody-based detections). Novel Strategies for Stratification and Treatment of Prostate Cancers:			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
• Continue to employ state-of-the-art clinical trials for the treatment of metastatic prostate cancers and develop new trials targeting prostate cancer driver genes, e.g., ERG. • Develop studies focusing on enhancing immunotherapy of prostate cancer. • Complete comprehensive evaluations of ERGi to support Phase I clinical trial. • Enhance biological understanding of less understood prostate cancer driver genes through cell culture based and engineered mouse models and tumorigenicity models for developing novel therapeutics. • Develop novel concepts, e.g., targeting the androgen receptor modulator, PMEPA1 gene in facilitating degradation of androgen receptor, a central player in development of castration resistant prostate cancer. • Develop multi-center evaluation of the CPDR androgen receptor function index (ARFI) gene panel towards earlier and more effective stratification of patients for androgen axis targeting drugs. Education and Training Program: • Continue investing in the training of next generation of DoD physicians and researchers. Leverage the strong track record in translational research training for medical researchers at DoD institutions, e.g., WRNMMC urology residents, post-doctoral fellows, USU Capstone medical and graduate students.			
FY 2019 Plans: Precision Medicine Focus: Continue to leverage long term assets of DoD patient database (30K subjects with up to 25 yrs of follow up) and biospecimen bank (230K aliquots) towards delineation of molecular markers to enhance treatment decisions through precision medicine with emphasis on racially diverse patients in equal access military healthcare system. Define prostate cancer prevention strategies by addressing the role of predisposing conditions military-specific exposures and genetic components in prostate cancer onset and progression of service members. Validate prediction models for disease progression, quality of life, and overall survival across the spectrum of cancer treatments and determine factors that predict definitive treatment for patients initially managed on active surveillance. Develop modalities for diagnosing and prognosing clinically significant prostate cancers to reduce over diagnosis and treatment, through molecular/clinico-pathologic prognostic signatures of MRI-ultrasound fusion image guided biopsy specimens. Enhance pre/post-operative follow-up for cancer diagnosis, progression, pain, mobility deficits and restoration of function through the CoE's long-term database.			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Continue to strengthen the Cancer Moonshot and APOLLO prostate cancer proteogenomics discovery and targeted therapy focus under the Murtha Cancer Center aligned with the national cancer precision medicine initiatives. Validate prognostic biomarker panels developed from biofluid-based metabolome, proteome and lipidome analyses addressing the limitations of currently used serum PSA diagnostic test in multi-center validation setting. Health Disparity Research: Continue to lead discoveries of prostate cancer causing genes for diagnosing, prognosing and targeted therapy of racially diverse DoD prostate cancer patients with indolent and aggressive disease. Leverage established key collaborations with DoD academy and industry to integrate whole genome, whole-transcriptome sequencing, proteome, lipidome and metabolome analyses on a large CPDR cohort of African American and Caucasian American patients. Delineate the prostate cancer genomic landscape of under studied African American, Asian and Hispanic patients towards the development of broadly applicable diagnostic, prognostic markers and treatment approaches. Develop innovative experimental models for establishing the mechanisms of newly discovered race/ethnicity associated prostate cancer genes towards ethnicity-informed therapeutic strategies. Continue to leverage established collaborations with NCI investigators addressing race/ethnicity associated genetic predisposition for metastatic prostate cancer. Development of Molecular Diagnostic and Prognostic Tools: Strengthen the CoE's unique DoD prostate cancer research resources by employing advanced informatics and logistic platforms for enhancing the integration of clinical, biospecimen and molecular databases towards the development of diagnostic and prognostic tools. Validate in multi-center setting the prognostic utility of CoE developed prostate cancer biomarkers including urine exosome-based mRNA panels, serum multi-omics based panels, cytogenetic tests and the ERG monoclonal antibody (e.g., urine exosomes clinical trial in collaboration with the Exosome Diagnostics Inc.). Continue to enhance knowledge of prostate cancer driver genes as exemplified by CoE leadership in the discovery/delineation of biological function and biomarker/ therapeutic utility of the most common prostate cancer gene, ERG.			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Expand the research on serum and urine based protein and omics-defined biomarkers including serum antigen- autoantibody-based and mass spectrometry-based detections. Novel Strategies for Stratification and Treatment of Prostate Cancers: Continue to employ state-of-the-art clinical trials and research evaluating novel therapies for androgen axis inhibitors and immuno/radiation therapy complemented by emerging approaches targeting newly discovered prostate cancer driver gene alterations (e.g., ERG and DNA repair gene defects). Evaluate strategies for enhancing immunotherapy of advanced prostate cancer. Complete developments of new small molecule ERG inhibitors in collaboration with Stanford Medical School to enter Phase I clinical trials. Develop innovative cell culture, engineered mouse models and tumorigenicity models for defining the mechanisms of prostate cancer driver genes with the objective of discovering new therapeutic opportunities. Leverage newly developed concepts of combination therapies targeting adaptive mechanisms of prostate cancer progression, e.g., androgen receptor (and its modulator, PMEPA1) in combination of TGF-beta inhibitors or NOTCH1 inhibitors in the context of early stage and advanced disease. Develop multi-center evaluation of the CPDR androgen receptor function index (ARFI) gene panel towards earlier and more effective stratification of patients for androgen axis targeting drugs. Education and Training Program: Leverage the strong track record in translational research training of the next generation of physicians, researchers, medical researchers at DoD institutions, e.g., WRNMMC urology residents, post-doctoral fellows, USU Capstone medical and graduate students. Enhance patient education focusing on quality-of-life, active surveillance and new treatment opportunities and integration with patient support groups. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	8.443	7.250	8.203

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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)*

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
398A: *CoE-Neuroscience Center of Excellence (USUHS)*	3.679	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

Note

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: CoE-Neuroscience Center of Excellence (USUHS) ***Description:*** The Military Clinical Neuroscience Center of Excellence (MCNCoE) is to improve prevention, diagnosis, and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions. The MCNCoE's approach to its goals includes supporting the research potential of military treatment facilities across the DOD system as well as the national capital area, and facilitating a network of collaborations between investigators across these facilities.	0.000	-	-
Accomplishments/Planned Programs Subtotals	0.000	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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)*

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	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 2017	FY 2018	FY 2019
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 2018 Plans:*** No funding programmed. ***FY 2019 Plans:*** No funding programmed. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** N/A	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 2019 Defense Health Agency		Date: February 2018
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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
431A: *Underbody Blast Testing (Army)*	38.742	1.869	8.000	10.800	-	10.800	9.200	1.400	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), 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 2017	FY 2018	FY 2019
Title: Underbody Blast Testing	1.869	8.000	10.800
Description: Testing will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or IED, and the biomedical basis for the development of a Warrior-representative blast test manikin and associated biomedically-validated injury criteria that can be used to characterize dynamic events and injury risks for LFT&E crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats.			
FY 2018 Plans: Biofidelity response corridors are being used to validate second generation prototypes of the WIAMan. Human injury assessment curves continue to be developed for the lower extremities, pelvis and spine from laboratory testing that created thresholds of cadaveric fractures and subsequent severe injuries (i.e., complex fractures). Laboratory testing to generate female post mortem human subject injury tolerances continue and are being used to inform the analysis of alternatives for developing a female specific manikin.			
FY 2019 Plans: FY 2019 plans continue efforts as outlined in FY 2018.			
FY 2018 to FY 2019 Increase/Decrease Statement:			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	1.869	8.000	10.800

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
448A: *Military HIV Research Program (Army)*	18.026	7.069	6.359	7.360	-	7.360	7.877	8.035	8.196	8.361	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: Military HIV Research Program	7.069	6.359	7.360
Description: The Military HIV Research Program aims to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. In addition, program also aims to develop other prevention and treatment strategies to mitigate the HIV epidemic globally. This project down-selects one or more vaccine candidates that are optimized through pre-clinical studies in non-human primates and conducts human clinical trials in Africa, Asia and the U.S. to test for safety and immunogenicity (ability to invoke an immune response), and early proof of concept efficacy testing.			
FY 2018 Plans: In FY18, plans are to extend an Early Capture HIV Cohort studies in Europe and Asia with the purpose of characterizing recruitment, retention, HIV prevalence, HIV incidence and biological characteristics of acute HIV infection in high-risk volunteers and extend human population studies to Asia, Europe and West Africa that will provide knowledge about the earliest HIV events to provide possible clues in developing preventive and/or therapeutic vaccines with the best combination of candidates of interest. This project will conduct human clinical trials in Europe, Africa, Asia and the US to test for safety and immunogenicity, and early proof of concept efficacy testing with selected vaccine candidates that have shown efficacy in non-human primate model.			
FY 2019 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
FY 2019 plans continue efforts as outlined in FY 2018. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	7.069	6.359	7.360

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
830A: *Deployed Warfighter Protection (Army)*	23.290	5.693	5.123	5.930	-	5.930	6.345	6.473	6.601	6.733	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 World Health Organization Global Malaria Program to lead development of new tools for insect-borne disease prevention.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: Deployed Warfighter Protection	5.693	5.123	5.930
Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects. ***FY 2018 Plans:*** In FY 2018 the DWFP research project continues to lead translational research to develop and field tools that protect against emerging infectious disease threats and enable deployed forces to enhance protection from biting insects, primarily mosquitoes and sand flies, which transmit force degrading diseases. The completion of the AFPMB Vector Control Capabilities Gap Analysis in FY 2016 is used to develop acquisition-based research and development requirements. The AFPMB develops test and evaluation plans necessary to determine a product's ability to meet the requirement. ***FY 2019 Plans:*** FY 2019 plans continue efforts as outlined in FY 2018. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	5.693	5.123	5.930

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 830A / *Deployed Warfighter Protection (Army)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 478 / *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
478: *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*	0.000	0.000	14.766	14.754	-	14.754	18.556	18.639	18.724	19.098	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: DoD Cancer Moonshot - Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)	0.000	14.766	14.754
Description: Description: DoD's Cancer Moonshot at USU's MCC is a research program consisting of two overall projects, the first known as APOLLO (Applied Organizational Learning and Outcomes), and the second as DoD Framingham. APOLLO is a novel high-throughput molecular analysis of every DNA (gene), RNA, and protein expression molecule in cancer patient tumors. Such analysis has never been done on a large scale across multiple cancer types, and small pilot studies demonstrate that the APOLLO project will result in unprecedented findings across all types of cancer (with specific focus on cancers of the greatest threat to ASDMs). These new findings will be identified by using state-of-the-art tissue collection procedures in the operating rooms of all patients undergoing cancer surgery at MCC collection protocol sites (e.g.. Walter Reed NMMC;NMC Portsmouth; NMC San Diego; Womack AMC; Keesler AFB) and, then, sequencing the entire DNA genome and RNA sequence at USU, while analyzing the entire protein expression profile of these same cancers in MCC's Proteomics Laboratory, as well as other affiliated protein laboratories. The vast molecular data that will be derived from these analyses (in the terabyte			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 478 / *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
and petabyte range and beyond) will be linked to clinical patient data as well as treatment outcomes data. These combined data sets will be housed in National Cancer Institute (NCI) secure cloud-based servers with restricted access for analytics by teams of bioinformatics experts (i.e., from government, university, and corporate entities) across the United States working on this endeavor. This complete bio molecular (global) expression profiling of thousands of cancers of all types seen in military treatment and other facilities will predictably result in a myriad of new discoveries regarding the way cancers develop, progress, respond to treatment, evade treatment, and spread. It also will result in new ways to combat cancers and minimize side effects of cancer treatment, as well as identify novel cancer screening and prevention opportunities, while focusing on militarily-relevant cancers and ADSMs with cancer, distinguishing it from any effort that might develop in the future in a civilian organization, as none of this scale exists today. There are five specific APOLLO sub-projects, which are classified based on the organ type of cancer under study: APOLLO 1 = Lung cancer; APOLLO 2 = Gynecological cancer; APOLLO 3 = Prostate cancer; APOLLO 4 = Breast cancer; and APOLLO 5 = all other cancer types. Both of these projects in the DoD Cancer Moonshot program were specifically developed to focus on ADSM with cancer (readiness), utilize molecular laboratories that are American owned and operated (U.S. DoD and DOE), keep all sensitive de-identified clinical and molecular data on U.S. government computers and servers for maximum data security and analysis (through the NCI), and benefit the nation through any and all discoveries that are made. ***FY 2018 Plans:*** APOLLO - Collect 1,000 cancer specimens (all cancer types) and run them though the DNA, RNA, and protein molecular analysis lab platforms of USU, and perform initial data analytics on the results. Perform final data analytics on previously analyzed APOLLO samples. ***FY 2019 Plans:*** APOLLO - FY 2019 plans continue efforts as outlined in FY 2018. Framingham – Identify Framingham 3 serum specimens and run them through the serum protein analysis lab platform, and perform initial data analytics on the results. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	0.000	14.766	14.754

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 478 / *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

To be determined.

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 479 / *Framingham Longitudinal Study (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
479: *Framingham Longitudinal Study (USUHS)*	0.000	0.000	4.920	4.920	-	4.920	4.920	4.920	4.920	5.018	Continuing	Continuing

A. Mission Description and Budget Item Justification

DoD Cancer Moonshot Program - DoD Framingham

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: DoD Cancer Moonshot Program - DoD Framingham Longitudinal Study	0.000	4.920	4.920
Description: DoD Framingham is a novel project that is enabled by the blood serum specimens stored at the DoD Serum Repository at the Armed Forces Health Surveillance Branch (AFHSB) in Silver Spring, Maryland. This facility stores blood serum drawn from over 10 million ADSMs who were required to undergo mandatory semiannual blood testing for the last 25 years, resulting in this repository with over 65 million blood serum specimens. MCC tumor registry data, which includes every ADSM who developed cancer while on active duty, is matched to data in the Serum Repository. This allows MCC to identify the blood serum of ADSMs who ultimately develop cancer at key times, i.e., before they had cancer, during their cancer treatment, and after their successful cancer treatment. Four different serum specimens (two before, one during, and one after cancer diagnosis and treatment) from every ADSM who developed certain types of cancer over a ten-year period of time are then sent to the Nation's foremost protein identification (mass spectroscopy) center, i.e., the Pacific Northwest National Laboratory (PNNL) run by the Department of Energy (DOE). This enables identification of the entire proteome circulating in the blood serum of these cancer patients before, during, and after cancer diagnosis. Comparing the proteomes will allow for identification of new protein biomarkers and indicators of treatment response and failure both of individual patients and across all patients with a specific type of cancer. Smaller studies of this nature done by MCC researchers have proven that this is an effective strategy to identify novel diagnostic and treatment protein expression biomarkers that can be assayed in new blood tests for cancer. This			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 479 / *Framingham Longitudinal Study (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
project will do it “at scale”, i.e. in large numbers of active duty cancer patients (who are otherwise healthy and therefore do not have the “confounding” protein markers of old age, diabetes, and other medical issues). By using serums that go back many years before the ADSM was diagnosed with cancer, the earliest markers of cancer that will be identified, and assays will be performed by another U.S. governmental agency with the best protein detection and analysis tools in the world. Eight specific DoD Framingham sub-projects, classified based on the organ type of cancer, will be conducted: Framingham 1 = Oropharyngeal cancer; Framingham 2 = Lymphoma; Framingham 3 = Bladder cancer; Framingham 4 = Kidney cancer; and Framinghams 5 through 8 subtypes will be determined by MCC and NCI experts in the coming months. Both the APOLLO and Framingham projects in the DoD Cancer Moonshot program were specifically developed to focus on ADSM with cancer (readiness), utilize molecular laboratories that are American owned and operated (U.S. DoD and DOE), keep all sensitive de-identified clinical and molecular data on U.S. government computers and servers for maximum data security and analysis (through the NCI), and benefit the nation through any and all discoveries that are made. ***FY 2018 Plans:*** Identify Framingham 2 (Lymphoma) serum specimens and run them through the serum protein analysis lab platform, and perform initial data analytics on the results. A de-identified dataset will be obtained from the Armed Forces Health Surveillance Branch related to serum samples identified by and pulled from the Department of Defense Serum Repository (DoDSR). This data set will include the following: 1) case status (i.e., case or control); 2) year of diagnosis; 3) year of the sample acquisition; 4) year of birth of the subject; 5) gender of the subject; 6) tumor stage at time of diagnosis for the cases; and 7) p16 status at time of diagnosis for the cases. If information on recurrences of the cancer for the case subjects is available, that will be provided as well (i.e., in yes/no format and with date of recurrence if applicable). Specimens to be used in this study will be serum samples from the DoDSR. The DoDSR is a repository of serially collected serum samples obtained from active duty service members from the time of their military in-processing through their discharge, taken at a minimum at two year intervals ***FY 2019 Plans:*** Identify Framingham 3 serum specimens and run them through the serum protein analysis lab platform, and perform initial data analytics on the results.			
Accomplishments/Planned Programs Subtotals	0.000	4.920	4.920

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 479 / *Framingham Longitudinal Study (USUHS)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance Metrics to be determined.

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 499 / *MHS Financial System Acquisition*	

COST ($ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
499: *MHS Financial System Acquisition*	0.000	1.766	13.456	21.129	-	21.129	5.373	1.971	2.011	2.051	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: MHS Financial System Acquisition	1.766	13.456	21.129
Description: The goal is to transition financial operations to a platform that allows for consistency across the Defense Health Agency, enabling standardized processes, data collection, and reporting. ***FY 2018 Plans:*** Research to consolidate all DHP appropriations into a single Financial Management System (FMS) system to provide the following capabilities: 1. Improved FMS functionality 2. Financial compliance and accountability 3. Improved business processes and enterprise data visibility 4. Improved cost management structure and financial reporting for the military medical system. ***FY 2019 Plans:*** FY 2019 plans continue efforts as outlined in FY 2018. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Additional research funding necessary to continue the consolidation all DHP appropriations into a single Financial Management System (FMS) system to provide the following capabilities:			
Accomplishments/Planned Programs Subtotals	1.766	13.456	21.129

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 499 / *MHS Financial System Acquisition*	

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
• BA 3: *PE 0807721 Replacement & Modernization*	0.000	9.031	10.409	-	10.409	22.611	0.000	0.000	0.000	Continuing	Continuing

Remarks

D. Acquisition Strategy

Acquisition Strategy is to be determined.

E. Performance Metrics

Performance metrics to be determined.

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 381 / *CoE - Integrative Cardiac Health Care (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
381: *CoE - Integrative Cardiac Health Care (USUHS)*	0.000	0.000	0.000	2.914	0.000	2.914	3.118	3.180	3.244	3.309	Continuing	Continuing

A. Mission Description and Budget Item Justification

The USU Integrative Cardiac Health Program is a Center of Excellence whose mission is to:
1. Improve force health by an improved understanding of the CVD risk susceptibility and adoption of healthy lifestyles in military-specific populations (e.g. Wounded Warriors) through leading-edge research using novel tools and biotechnologies.
2. Investigate and create transformational models of practical and personalized CVD prevention tracks as an adjunct to traditional care for dissemination to MHS.
3. Refine individualized prevention strategies through "big Data" modeling to define the most cost-effective and sustainable approaches in promoting CV health throughout the military lifecycle.
4. Identify precise strategies for early detection, monitoring and reduction of preclinical/clinical CV and related chronic disease risks for improved clinical outcomes.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: Integrative Cardiac Health Center of Excellence	0.000	0.000	2.914
Description: USU is a “central focal point for health-related education and training, research and scholarship, and leadership support to operational military units around the world” and is the ideal engine to establish a strategic partnership to address cardiovascular health. ***FY 2018 Plans:*** No funding programmed. Beginning in FY19, the ICHP funding line is transferred from the Army to USUHS Project 381. ***FY 2019 Plans:*** The Integrative Cardiac Health Center of Excellence (ICHP) will continue development and refinement of 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) interventions specifically designed for the military and the effects of these interventions on preclinical atherosclerosis (plaque in arteries). Precision medicine efforts exploring novel biomolecular markers and tests as indicators for early (preclinical) cardiovascular disease risk assessment will continue. Will characterize new clinical phenotypes; detect cardiovascular disease in early stages when it is more likely to be reversible. ICHP will collaborate with Walter Reed Bethesda Cardiovascular Service, the Mayo Clinic, Abbott Laboratories, and Integrative Systems Biology for these efforts. ICHP will use this information to tailor personalized health interventions and build resiliency in the military population before disease affects quality of life. The Wounded Warriors project will continue to examine cardiovascular risk in the amputee and injured Warfighter and begin analysis of bio-samples collected to detect novel biomolecular markers. Study is			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 381 / *CoE - Integrative Cardiac Health Care (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
designed to significantly advance the precision of risk detection and lead to an improvement of current interventions and patient outcomes. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Beginning in FY19, the ICHP funding line is transferred from the Army to USUHS Project 381.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	2.914

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

Integrative Cardiac Health Care Center of Excellence performance has been 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. Additional performance metrics may be developed after the strategic alliance has been formalized.

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 504 / *WRAIR Vaccine Production Facility Research*	

COST ($ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
504: *WRAIR Vaccine Production Facility Research*	-	0.000	0.000	8.000	-	8.000	8.152	8.315	8.481	8.651	Continuing	Continuing

A. Mission Description and Budget Item Justification

The WRAIR Vaccine Pilot Bioproduction Facility (PBF) is the Department of Defense's only facility capable of producing good manufacturing practices (GMP) quality biologic products for use in early phase clinical trials. The mission of the WRAIR PBF is to support the development and licensure of vaccines and relevant biologics critical to the global health of our Warfighters serving domestically or abroad in compliance with US Food and Drug Administration (FDA) regulations. Funding supports a baseline level of preparedness for vaccine production and improved response-time in the setting of known and emerging infectious disease threats needing a preventive countermeasure while working with a collaborative network of partners. This project supports vaccine development efforts of strategic importance to the DoD, including Service medical research and development programs, those of other DoD organization such as the Defense Threat Reduction Agency and the Defense Advanced Research Projects Agency, and pandemic biopreparedness for emerging infectious disease threats in the Global Health Security Agenda.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2017	FY 2018	FY 2019
Title: WRAIR Vaccine Production Facility	0.000	-	8.000
Description: The WRAIR Vaccine Pilot Bioproduction Facility (PBF) will focus on the manufacture of early phase clinical materials for vaccine production from varied platforms, such as live virus, conjugates, recombinant proteins, DNA, and monoclonal antibody approaches that: (a) expand collaborative partnerships for product development that meet DoD requirements; (b) open active intramural-based discovery efforts of new products for development; and (c) initiate and extend strategic partnerships with external collaborators (Government and industry) to develop/co-develop potential new biologic approaches to pandemic disease preparedness. ***FY 2019 Plans:*** Complete commissioning and validation of the renovated facility and resume vaccine and biologic production efforts. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** The PBF research will begin in FY 2019.			
Accomplishments/Planned Programs Subtotals	0.000	-	8.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 504 / *WRAIR Vaccine Production Facility Research*

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance of the WRAIR PBF program is measured by the number of products used in clinical trials, number of pilot lots produced (for USG, DoD, and non-federal partners), number of doses vialed, and other biologics produced. Additionally, the WRAIR PBF program will conduct an annual research review during which a panel of DoD subject matter experts provide input on programmatic alignment and strategic priorities.