

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	6,263.841	1,499.497	1,647.789	279.421	-	279.421	269.473	274.476	279.965	285.564	Continuing	Continuing
300A: CSI - Congressional Special Interests	5,000.553	1,022.296	1,122.869	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
238C: Enroute Care Research & Development (Budgeted) (AF)	18.642	4.479	6.833	8.088	-	8.088	8.249	8.418	8.586	8.758	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)	4.264	1.548	0.000	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)	2.544	1.238	0.000	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)	13.716	5.327	5.523	5.633	-	5.633	5.745	5.859	5.976	6.096	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)	23.108	2.699	4.702	5.514	-	5.514	5.624	5.736	5.851	5.968	Continuing	Continuing

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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)	56.140	9.504	9.725	9.919	-	9.919	10.118	10.319	10.525	10.736	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)	15.546	4.554	4.645	4.737	-	4.737	4.833	4.929	5.028	0.000	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)	40.591	7.373	8.327	10.209	-	10.209	10.413	10.621	10.833	11.051	Continuing	Continuing
373A: GDF - Medical Technology Development	644.307	361.925	378.578	78.868	-	78.868	86.986	90.154	91.959	93.798	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

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378B: CoE-Breast Cancer Center of Excellence (USU)	10.552	9.088	10.280	10.475	-	10.475	10.685	10.898	11.116	11.339	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)	9.226	7.943	8.987	9.158	-	9.158	9.341	9.528	9.719	9.913	Continuing	Continuing
381A: CoE-Integrative Cardiac Health Care Center of Excellence (Army)	18.083	2.697	0.000	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)	8.079	2.822	3.310	3.376	-	3.376	3.445	3.514	3.584	3.656	Continuing	Continuing
383A: CoE-Prostate Cancer Center of Excellence (USUHS)	41.822	7.250	8.203	8.359	-	8.359	8.526	8.696	8.870	9.047	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)	40.611	8.000	10.800	9.200	-	9.200	1.400	0.000	0.000	0.000	-	-
448A: Military HIV Research Program (Army)	25.095	6.359	7.360	7.877	-	7.877	8.035	8.196	8.361	8.528	Continuing	Continuing
830A: Deployed Warfighter Protection (Army)	28.983	5.123	5.930	6.345	-	6.345	6.473	6.601	6.733	6.868	Continuing	Continuing
478: Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)	0.000	14.766	14.754	18.556	-	18.556	18.639	18.724	19.098	19.480	Continuing	Continuing

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479: Framingham Longitudinal Study (USUHS)	0.000	4.920	4.920	4.920	-	4.920	4.920	4.920	5.018	5.118	Continuing	Continuing
499: MHS Financial System Acquisition	1.766	13.456	21.129	15.373	-	15.373	1.971	2.011	2.051	2.092	Continuing	Continuing
381: CoE - Integrative Cardiac Health Care (USUHS)	0.000	0.000	2.914	3.118	-	3.118	3.180	3.244	3.309	3.375	Continuing	Continuing
504: WRAIR Vaccine Production Facility Research	0.000	0.000	8.000	8.152	-	8.152	8.315	8.481	8.651	8.824	Continuing	Continuing
506: Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)	-	0.000	0.000	11.904	-	11.904	12.141	12.385	12.631	12.883	Continuing	Continuing
507: Brain Injury and Disease Prevention, Treatment and Research (USUHS)	-	0.000	0.000	13.317	-	13.317	13.583	13.855	14.132	14.415	Continuing	Continuing
508: Psychological Health and Resilience (USUHS)	-	0.000	0.000	7.000	-	7.000	7.140	7.283	7.428	7.577	Continuing	Continuing
509: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)	-	0.000	0.000	19.323	-	19.323	19.710	20.104	20.505	20.916	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												

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Appropriation/Budget Activity	R-1 Program Element (Number/Name)	
0130: Defense Health Program / BA 2: RDT&E	PE 0603115DHA / Medical Technology Development	
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.		

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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.		

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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115DHA I <i>Medical Technology Development</i>
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B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	245.936	274.920	269.421	-	269.421
Current President's Budget	245.936	274.920	269.421	-	269.421
Total Adjustments	0.000	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	-	-			

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

Project: 300A: *CSI - Congressional Special Interests*

Congressional Add: 245A - *Amyotrophic Lateral Sclerosis (ALS) Research*

Congressional Add: 293A - *Autism Research*

Congressional Add: 296A - *Bone Marrow Failure Disease Research*

Congressional Add: 310A - *Peer-Reviewed Ovarian Cancer Research*

Congressional Add: 328A - *Peer-Reviewed Multiple Sclerosis Research*

Congressional Add: 335A - *Peer-Reviewed Cancer Research*

Congressional Add: 336A - *Peer-Reviewed Lung Cancer Research*

Congressional Add: 337A - *Peer-Reviewed Orthopaedic Research*

Congressional Add: 338A - *Peer-Reviewed Spinal Cord Research*

Congressional Add: 339A - *Peer-Reviewed Vision Research*

Congressional Add: 352A - *Traumatic Brain Injury/Psychological Health Research*

Congressional Add: 380A - *Peer-Reviewed Breast Cancer Research*

Congressional Add: 390A - *Peer-Reviewed Prostate Cancer Research*

Congressional Add: 392A - *Gulf War Illness Peer-Reviewed Research*

Congressional Add: 396A - *Research in Alcohol and Substance Use Disorders*

Congressional Add: 400A - *Peer-Reviewed Medical Research*

Congressional Add: 417A - *Peer-Reviewed Alzheimer Research*

FY 2018	FY 2019
9.665	10.000
7.248	7.500
2.900	3.000
19.329	20.000
5.799	6.000
77.316	90.000
13.530	14.000
28.994	30.000
28.994	30.000
14.497	20.000
105.947	99.269
125.638	130.000
96.645	100.000
20.332	22.000
3.865	4.000
319.039	350.000
14.497	15.000

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Congressional Add Details (\$ in Millions, and Includes General Reductions)		FY 2018	FY 2019
Congressional Add: 439A - <i>Joint Warfighter Medical Research</i>		26.695	27.500
Congressional Add: 452A - <i>Peer-Reviewed Reconstructive Transplant Research</i>		11.597	12.000
Congressional Add: 454A - <i>Orthotics and Prosthetics Outcomes Research</i>		9.665	10.000
Congressional Add: 456A - <i>HIV/AIDS Program</i>		12.473	12.900
Congressional Add: 459A - <i>Peer-Reviewed Epilepsy Research</i>		7.248	7.500
Congressional Add: 463A – <i>Program Increase: Restore Core Research Funding Reduction (GDF)</i>		0.000	-
Congressional Add: 495 - <i>Peer-Reviewed Tick-Borne Disease Research</i>		4.832	5.000
Congressional Add: 496 - <i>Trauma Clinical Research Program</i>		9.665	10.000
Congressional Add: 501 - <i>Peer-Reviewed Hearing Restoration Research (Army)</i>		9.665	10.000
Congressional Add: 502 - <i>CSI - Peer-Reviewed Kidney Cancer Research (Army)</i>		14.497	20.000
Congressional Add: 503 - <i>CSI - Peer-Reviewed Lupus Research (Army)</i>		4.832	5.000
Congressional Add: 540A - <i>Global HIV/AIDS Prevention (Navy)</i>		8.000	8.000
Congressional Add: 660A - <i>Tuberous Sclerosis Complex (TSC)</i>		5.799	6.000
Congressional Add: 790A - <i>Peer-Reviewed Duchenne Muscular Dystrophy</i>		3.093	3.200
Congressional Add: 512 - <i>Peer-Reviewed Melanoma Research</i>		-	10.000
Congressional Add: 513 - <i>Chronic Pain Management</i>		-	10.000
Congressional Add: 514 - <i>Combat Readiness Medical Research</i>		-	15.000
Congressional Add Subtotals for Project: 300A		1,022.296	1,122.869
Project: 506: <i>Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)</i>			
Congressional Add:		0.000	-
Congressional Add Subtotals for Project: 506		0.000	-
Project: 509: <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i>			
Congressional Add:		0.000	-
Congressional Add Subtotals for Project: 509		0.000	-
Congressional Add Totals for all Projects		1,022.296	1,122.869

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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).		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
300A: CSI - Congressional Special Interests	5,000.553	1,022.296	1,122.869	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

In FY 2018, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2018	FY 2019
Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research FY 2018 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 2018: the Therapeutic Development Award and the Therapeutic Idea Award. Applications were received in August 2018 followed by scientific peer review in October 2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019. FY 2019 Plans:	9.665	10.000
Congressional Add: 293A - Autism Research FY 2018 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 2018: the Clinical Trial Award, the Clinical Translational Research Award, and the Idea Development Award. Applications will be received in October 2018 followed by scientific peer review in January 2019. Funding recommendations will be made at programmatic review in March 2019. Awards will be made by September 2019. FY 2019 Plans:	7.248	7.500
Congressional Add: 296A - Bone Marrow Failure Disease Research	2.900	3.000

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B. Accomplishments/Planned Programs (\$ in Millions)		
		FY 2018
		FY 2019
<i>FY 2018 Accomplishments:</i> 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 2018, applications were accepted through one funding opportunity, the Idea Development Award, released in May 2018 . Applications will be received in October 2018 followed by scientific peer review in November 2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019.		
<i>FY 2019 Plans:</i>		
<i>Congressional Add:</i> 310A - Peer-Reviewed Ovarian Cancer Research		
<i>FY 2018 Accomplishments:</i> 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 2018 OCRP solicited 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 2018: Pilot Award, Clinical Development Award, Investigator-Initiated Research Award, and the Ovarian Cancer Academy Award recruiting Early-Career Investigators. Applications were received in August 2018 for the Pilot Award and in September 2018 for the remaining three mechanisms. Scientific peer review will be in October 2018. Funding recommendations will be made at the programmatic reviews in December 2018. Awards will be made by September 2019.		19.329
<i>FY 2019 Plans:</i>		20.000
<i>Congressional Add:</i> 328A - Peer- Reviewed Multiple Sclerosis Research		5.799
<i>FY 2018 Accomplishments:</i> 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 2018 MSRP solicited applications that address the following areas: 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 2018: Exploration Hypothesis Development Award, and Investigator-Initiated Research Award. Applications were received in October 2018 followed by scientific peer review in December		6.000

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B. Accomplishments/Planned Programs (\$ in Millions)		
2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 335A - Peer-Reviewed Cancer Research		
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for the study of cancers designated by Congress: adrenal cancer; bladder cancer; blood cancers; brain cancer; colorectal cancer; immunotherapy; Listeria-based regimens for cancer; liver cancer, lymphoma; melanoma and other skin cancers; mesothelioma; myeloma; 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 June 2018: Career Development Award, Idea Award with Special Focus, Translational Team Science Award, and Expansion Award. Applications will be received in September 2018 followed by scientific peer review in November/December 2018. Funding recommendations will be made at programmatic review in February 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 336A - Peer-Reviewed Lung Cancer Research		
FY 2018 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 2018: 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 2018 followed by scientific peer review in October and November 2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 337A - Peer-Reviewed Orthopaedic Research		
FY 2018 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		
	FY 2018	FY 2019
	77.316	90.000
	13.530	14.000
	28.994	30.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
2018 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 2018: Clinical Trial Award, Clinical Translational Research Award, Integrated Clinical Trial Award, Expansion Award, and Applied Research Award. Pre-applications were received in July 2018 and applications will be received in September 2018, followed by scientific peer review in November 2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019.			
FY 2019 Plans:			
Congressional Add: 338A - Peer-Reviewed Spinal Cord Research		28.994	30.000
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for spinal cord injury (SCI) research. The FY 2018 Spinal Cord Injury Research Program 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 2018: Clinical Research Development Award, Clinical Trial Award, Investigator-Initiated Research Award, Qualitative Research Award, and Translational Research Award. Pre-applications were received August 2018 and applications will be received in November 2018, followed by scientific peer review in January 2019. Funding recommendations will be made at programmatic review in March 2019. Awards will be made by September 2019.			
FY 2019 Plans:			
Congressional Add: 339A - Peer-Reviewed Vision Research		14.497	20.000
FY 2018 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 2018 Vision Research Program focused on the following areas: (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,			

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PE 0603115DHA: *Medical Technology Development*
Defense Health Agency

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
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 2018: 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 2018, scientific peer reviews in August and October 2018 and February 2019, and programmatic reviews in October and December 2018 and January, April, and May 2019. Awards will be made by September 2019. FY 2019 Plans:			
Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for prostate cancer research. The vision for the FY 2018 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 were 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. Seven award mechanisms were released in May 2018: 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 2018, followed by scientific peer reviews in October, November, and December 2018. Funding recommendations will be made at programmatic reviews in January and February 2019. Awards will be made by September 2019. FY 2019 Plans:		96.645	100.000
Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for Gulf War Illness research. The vision for the FY 2018 Gulf War Illness Research Program was improving the health and lives		20.332	22.000

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
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 2018: Biorepository Resource Network Award, Clinical Consortium Award, Investigator-Initiated Focused Research Award, and Qualitative Research Award. Applications will be received in September 2018 followed by scientific peer review in November 2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019.			
FY 2019 Plans:			
Congressional Add: 396A - Research in Alcohol and Substance Use Disorders		3.865	4.000
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for alcohol and substance use disorders (ASUD) research. The goal of the FY 2018 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). In support, the Consortium Award Program Announcement was released in June 2018. Applications were received in September 2018, followed by scientific peer review in November 2018 and programmatic review in January 2019. Awards will be made by September 2019.			
FY 2019 Plans:			
Congressional Add: 400A - Peer-Reviewed Medical Research		319.039	350.000
FY 2018 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 52 Congressionally-directed topics for FY 2018 were: Acute Lung Injury, Antimicrobial Resistance, Arthritis, Burn Pit Exposure, Cardiomyopathy, Cerebellar Ataxia, Chronic Migraine and Post-traumatic Headache, Chronic Pain Management, Congenital Heart Disease, Constrictive Bronchiolitis, Diabetes, Dystonia, Eating Disorders, Emerging Infectious Diseases, Endometriosis, Epidermolysis Bullosa, Focal Segmental Glomerulosclerosis, Fragile X, Frontotemporal Degeneration, Guillain-Barre Syndrome, Hepatitis B and C, Hereditary Angioedema, Hydrocephalus, Immunomonitoring of Intestinal Transplants, Inflammatory Bowel Diseases, Interstitial Cystitis, Lung Injury, Malaria, Metals Toxicology, Mitochondrial Disease, Musculoskeletal Disorders, Myotonic Dystrophy, Non-Opioid Pain Management, Nutrition Optimization, Pancreatitis, Pathogen-Inactivated Blood Products, Post-Traumatic Osteoarthritis, Pressure Ulcers, Pulmonary Fibrosis, Respiratory Health, Rett Syndrome, Rheumatoid Arthritis, Scleroderma, Sleep Disorders, Spinal Muscular Atrophy, Sustained-Release Drug Delivery, Tinnitus, Tissue Regeneration, Tuberculosis, Vaccine Development for Infectious Diseases, Vascular Malformations, and Women's Heart			

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B. Accomplishments/Planned Programs (\$ in Millions)		
Disease. Five award mechanisms were offered in FY 2018: 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 2018, scientific peer review was conducted in August - September 2018, and funding recommendations will be made during programmatic review in November 2018. For the remaining mechanisms, application receipt will occur in October 2018, peer review will be conducted in November - December 2018, and funding recommendations will be made during programmatic review in February 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 417A - Peer-Reviewed Alzheimer Research		
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for Alzheimer's disease (AD) research. The FY 2018 Peer-Reviewed Alzheimer's Research Program (PRARP) sought to: (1) address the long-term consequences of traumatic brain injury (TBI) as they pertain to AD and AD-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 2018: Convergence Science Research Award, Quality of Life Research Award, New Investigator Award, and Research Partnership Award. Applications will be received in September 2018, followed by peer review in November 2018. Funding recommendations will be made at programmatic review in February 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 439A - Joint Warfighter Medical Research		
FY 2018 Accomplishments: The FY 2018 Joint Warfighter Medical Research Program (JWMRP) provides continuing support for promising projects previously funded by Congressional Special Interest 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 2018 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.		
FY 2019 Plans:		
Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research		
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for reconstructive transplantation research. The FY 2018 Reconstructive Transplant Research Program (RTRP) focused		

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)		
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 2018: Concept Award, Investigator-Initiated Research Award (IIRA), Technology Development Award (TDA), and Qualitative Research Award (QRA). Applications will be received in December 2018. Peer review will take place in January 2019, and Programmatic Review will take place in March - April 2019. Awards will be made by September 2019.	FY 2018	FY 2019
FY 2019 Plans:		
Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for orthotics and prosthetics outcomes research. The goal of the FY 2018 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 focused on outcomes-based best practices through analysis of the merits of prosthetic and orthotic devices 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 was released in September 2018: Orthotics and Prosthetics Outcomes Research Award. Pre-applications will be received in October 2018 and applications in January 2019. Scientific peer review will be held in February 2019, and programmatic review will occur in April 2019. Awards will be made by September 2019. FY 2019 Plans:	9.665	10.000
Congressional Add: 456A - HIV/AIDS Program FY 2018 Accomplishments: FY 2019 Plans:	12.473	12.900
Congressional Add: 459A - Peer-Reviewed Epilepsy Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for traumatic brain injury (TBI)-related epilepsy research. The FY 2018 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	7.248	7.500

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B. Accomplishments/Planned Programs (\$ in Millions)		
into psychogenic (non-epileptic) seizures. Two award mechanisms were released for FY 2018: the Idea Development Award and Epilepsy Risk Factors Award. Applications were received in September 2018. Peer review will be held in November 2018, and programmatic review in February 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF)		
FY 2018 Accomplishments: This Congressional Special Interest initiative was directed toward FY 2018 DHP core research initiatives in PE 0603115. Funds supported medical technology development efforts in the areas of military operational medicine, combat casualty care, military infectious diseases, clinical and rehabilitative medicine, medical simulation and information sciences, and radiation health effects. (Project 373A).		
Congressional Add: 495 - Peer-Reviewed Tick-Borne Disease Research		
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for tick-borne diseases research. The FY 2018 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 illnesses and on delivering innovative solutions to prevent and better diagnose and treat their manifestations. Two funding opportunities were released in May 2018: Idea Award and Investigator-Initiated Research Award. Pre-applications were received in July 2018 and applications will be received in October 2018. Scientific peer review will be held in December 2018, and funding recommendations will be made at programmatic review in February 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 496 -Trauma Clinical Research Program		
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for advancing trauma clinical research. Through a competitive Request for Proposals (RFP) process, the Department of Defense (DoD) has created a coordinated, multi-institutional 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 DoD. 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 FY18, a panel of subject matter experts from the DoD (including representatives from the Combat Casualty Care		
	FY 2018	FY 2019
	0.000	-
	4.832	5.000
	9.665	10.000

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B. Accomplishments/Planned Programs (\$ in Millions)		
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. New DoD-relevant research task orders for the LITES network will be executed by September 2019.		
FY 2019 Plans:		
Congressional Add: 501 - Peer-Reviewed Hearing Restoration Research (Army)		
FY 2018 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 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. Two program announcements will be released in September 2018: Translational Research Award and Focused Research Award. Applications will be received in November 2018 with peer review in January 2019 and programmatic review in March 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 502 - CSI - Peer-Reviewed Kidney Cancer Research (Army)		
FY 2018 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. Four program announcements will be released in October 2018: Idea Development Award, Concept Award, Translational Research Partnership Award, and the Consortium Development Award. Applications will be received in January 2019 with peer review in February 2019 and programmatic review in April 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 503 - CSI - Peer-Reviewed Lupus Research (Army)		
FY 2018 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. Two program announcements will be released in October 2018: Concept Award and Idea		

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B. Accomplishments/Planned Programs (\$ in Millions)		
Award. Applications will be received in January 2019 with peer review in February 2019 and programmatic review in April 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 540A - Global HIV/AIDS Prevention (Navy)		8.000
FY 2018 Accomplishments:		
FY 2019 Plans:		
Congressional Add: 660A - Tuberous Sclerosis Complex (TSC)		5.799
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for Tuberous Sclerosis Complex (TSC) research. The FY 2018 Tuberous Sclerosis Complex Research Program (TSCRCP) 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 2018: Idea Development Award, Exploration-Hypothesis Development Award, and Clinical Translational Research Award. Applications were received in July 2018, followed by scientific peer review in September 2018. Funding recommendations will be made at programmatic review in November 2018. Awards will be made by September 2019.		6.000
FY 2019 Plans:		
Congressional Add: 790A - Peer-Reviewed Duchenne Muscular Dystrophy		3.093
FY 2018 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 2018 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 2018: Career Development Award and Investigator-Initiated Research Award. Applications will be received in October 2018 with scientific peer review to be conducted in January 2019 followed by programmatic review in March 2019. Awards will be made by September 2019.		3.200
FY 2019 Plans:		
Congressional Add: 512 - Peer-Reviewed Melanoma Research		-
		10.000

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
FY 2019 Plans: Not yet established.		
Congressional Add: 513 - Chronic Pain Management FY 2019 Plans: Not yet established.	-	10.000
Congressional Add: 514 - Combat Readiness Medical Research FY 2019 Plans: Not yet established	-	15.000
Congressional Adds Subtotals	1,022.296	1,122.869

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

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 238C / Enroute Care Research & Development (Budgeted) (AF)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
238C: Enroute Care Research & Development (Budgeted) (AF)	18.642	4.479	6.833	8.088	-	8.088	8.249	8.418	8.586	8.758	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 2018	FY 2019	FY 2020
Title: Enroute Care Research & Development (Budgeted) (AF)	4.479	6.833	8.088
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 2019 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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency							Date: February 2019				
Appropriation/Budget Activity 0130 / 2				R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>			Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i>				
B. Accomplishments/Planned Programs (\$ in Millions)							FY 2018	FY 2019	FY 2020		
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. <i>FY 2020 Plans:</i> FY 2020 plans continue efforts as outlined in FY 2019. <i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> 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							4.479	6.833	8.088		
C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020 Base</u>	<u>FY 2020 OCO</u>	<u>FY 2020 Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, PE 0807714HP: <i>Other Consolidated Health Support</i>	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.)											

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i>
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.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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 (TC CET) 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 243A / <i>Medical Development (Lab Support) (Navy)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
243A: <i>Medical Development (Lab Support) (Navy)</i>	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 2018	FY 2019	FY 2020	
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												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
247A: Elimination of Malaria in Southeast Asia (CARB) (Navy)	4.264	1.548	0.000	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 2018	FY 2019	FY 2020	
Title: Elimination of Malaria in Southeast Asia (CARB) (Navy)									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 2018 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 Jul 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 2019 Plans:												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 247A / <i>Elimination of Malaria in Southeast Asia (CARB) (Navy)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
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 be completed by the end of FY19, therefore, no funding is budgeted in the years following. <i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> The project will be completed by the end of FY19, therefore, no funding is budgeted in the years following.			
Accomplishments/Planned Programs Subtotals		1.548	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 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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
247B: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)	2.544	1.238	0.000	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 Naval Medical Research Center (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 2018	FY 2019	FY 2020	
Title: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)									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 2018 Accomplishments: FY 2018 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,												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 247B / <i>Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
4) describe the treatment strategies currently in use, and 5) assess the long-term sequelae. Adult patients with suspected infection and evidence of systemic inflammation were considered for enrollment. Laboratory testing augmented the testing routinely performed at the hospital microbiology laboratory, and included diagnostic tests (e.g. blood cultures, malaria smears, HIV tests, and serology), molecular diagnostics, 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 2019 Plans: FY18/19 funding will continue the support of the observational study at the Takeo Provincial Hospital in Cambodia and Komfo Anoke Teaching Hospital in Ghana. 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 combined with prognostic markers for sepsis and common pathogenic pathway data to achieve improved patient outcomes. The project will be completed by the end of FY19, therefore, no funding is budgeted in the years following. FY 2019 to FY 2020 Increase/Decrease Statement: The project will be completed by the end of FY19, therefore, no funding is budgeted in the years following.			
Accomplishments/Planned Programs Subtotals		1.238	0.000
C. Other Program Funding Summary (\$ in Millions)			
N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 247B / <i>Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)</i>
C. Other Program Funding Summary (\$ in Millions)		
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.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
284B: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)	13.716	5.327	5.523	5.633	-	5.633	5.745	5.859	5.976	6.096	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 2018	FY 2019	FY 2020
Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF) 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 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 2020 Plans:	5.327	5.523	5.633

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 284B / <i>USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals		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.)			
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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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.												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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.***												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
285A: Operational Medicine Research & Development (Budgeted) (AF)	23.108	2.699	4.702	5.514	-	5.514	5.624	5.736	5.851	5.968	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 2018	FY 2019	FY 2020	
Title: Operational Medicine Research & Development (Air Force)									2.699	4.702	5.514	
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 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 2020 Plans:												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 285A / <i>Operational Medicine Research & Development (Budgeted) (AF)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
FY 2020 plans continue efforts as outlined in FY 2019.			
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Increase reflects right-sizing the program funding to reflect the actual execution of the program.			
Accomplishments/Planned Programs Subtotals		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.)			
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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 285B / <i>Core Operational Medicine R&D - Clinical Translational Focus (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
285B: <i>Core Operational Medicine R&D - Clinical Translational Focus (AF)</i>	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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 285C / <i>Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
285C: <i>Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)</i>	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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
307B: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)	56.140	9.504	9.725	9.919	-	9.919	10.118	10.319	10.525	10.736	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 2018	FY 2019	FY 2020
Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force)	9.504	9.725	9.919
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			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
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 2018	FY 2019	FY 2020
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 2019 Plans: 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 collect exposure and health care data from multiple sources and transmit that data in a compressed format. FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019. FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.				
Accomplishments/Planned Programs Subtotals		9.504	9.725	9.919

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 307B / <i>Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)</i>
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.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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.)

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 307C / <i>Core Force Health Protection R&D - Clinical Translational Focus (AF)</i>
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.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
308B: Expeditionary Medicine Research & Development (Budgeted) (AF)	15.546	4.554	4.645	4.737	-	4.737	4.833	4.929	5.028	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)	FY 2018	FY 2019	FY 2020
Title: Expeditionary Medicine Research & Development (Air Force) 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 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	4.554	4.645	-

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 308B / <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
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 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 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals		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.)			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 308B / <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>

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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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.												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
309A: Regenerative Medicine (USUHS)	40.591	7.373	8.327	10.209	-	10.209	10.413	10.621	10.833	11.051	Continuing	Continuing
A. Mission Description and Budget Item Justification												
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 2018	FY 2019	FY 2020	
Title: Regenerative Medicine (USUHS)									7.373	8.327	10.209	
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 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												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 309A / <i>Regenerative Medicine (USUHS)</i>	

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
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. <i>FY 2020 Plans:</i> FY 2020 plans continue efforts as outlined in FY 2019. <i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Previous years reflect a programmatic reduction in RDT&E (DHP-wide).			
Accomplishments/Planned Programs Subtotals	7.373	8.327	10.209

C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-1, 0806721HP: <i>Uniformed Services University of the Health Sciences</i>	9.458	9.647	9.840	-	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.											

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
373A: GDF - Medical Technology Development	644.307	361.925	378.578	78.868	-	78.868	86.986	90.154	91.959	93.798	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 2018	FY 2019	FY 2020
Title: GDF – Medical Technology Development	126.790	128.578	78.868
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 2019 Plans: Medical simulation and information sciences technology maturation progressing to focus on developing and integrating pharmacodynamics (effects of drugs and the mechanism of their action) and pharmacokinetics (movement of drugs within the body) algorithms into an open source physiology research engine 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 on 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. Continuing efforts 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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency			Date: February 2019		
Appropriation/Budget Activity 0130 / 2		R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>		Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
Military infectious diseases progressing research 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. Ongoing multi-year studies addressing critical research focus areas in wound infections, such as improved treatment options for infections with multi-drug resistant organisms, 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 to be evaluated for down-selection. Efforts continuing 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. Research progresses to refine and improve predictive auditory injury models in order to update acoustic injury standards for health hazard assessment. Efforts 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 are ongoing. Progressing data collecting to improve multisensory cueing criteria for aircrew performance optimization in degraded visual environments. Research focuses to evaluate longitudinal data collected for dietary supplement use with correlation to usage patterns with associated negative and positive health effects. Research focuses to provide guidance on the effects of healthy cooking for food choice behaviors, nutritional status, and psychological states in Wounded Warriors and their families. Also, studies continue evaluating the physical demands associated with selection to historically male military occupations to develop gender-neutral Military Occupational Specialty assignment standards. Ongoing 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. Efforts toward delivery of interventions to prevent suicide behaviors and conduct clinical trials to test the efficacy of the interventions are progressing. Studies aimed at delivering resilience building/prevention programs focused on education, skills, and novel service delivery methods for Service member and Family resilience are ongoing. Newly developed and existing large-scale PTSD datasets and state-of-the-art analytic methods are being used to produce individualized treatment guidelines for PTSD as well as PTSD-related sleep disturbances. Candidate biomarkers validation of exposure to inhaled or ingested toxic substances and develop medical guidance for risk assessment of adverse health outcomes are ongoing. Research continues its focus to provide validated metrics for optimized operational task performance in extreme environments. Efforts to validate novel methods for estimating thermal strain from non-invasive measures are progressing. 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, progressing work 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. Animal studies are ongoing to evaluate oxygen delivery solutions infused to maintain survivability for potential use in severe casualties where blood transfusion					

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency			Date: February 2019		
Appropriation/Budget Activity 0130 / 2		R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>		Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
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 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 continues. Furthermore, neurotrauma research to investigate the impact of pre-injury conditions and the environment on Service member response to treatment and recovery following TBI. The program is leveraging data from Combat Operations to improve management of TBI by correlating injury events and medical records. Treatments for extremity trauma to develop specialized fracture stabilization techniques, address treatments for organ support and stabilization of craniomaxillofacial wounds will proceed to mature. Pre-hospital Tactical Combat Casualty Care will develop enhanced surgical procedures and equipment. En Route Care research will progress the development of specifications for an integrated system to support safe patient care and hand-offs, and the development of expanded en route care interventions and treatment capabilities. The military medical photonics program continues to develop light-based technologies and systems for combat casualty care, to include applications to detect 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 and the post-surgical benefits of photochemical bonding (the use of light to create new molecular bonds) in reducing scarring and adhesions are being studied. Research is being conducted on 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. 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 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019. FY 2019 to FY 2020 Increase/Decrease Statement: Project 373A funding was realigned to establish new enduring research efforts at the Uniformed Services University of the Health Sciences beginning in FY2020.					

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
- Health Research for Improved Medical Readiness and Healthcare Delivery (Project 506) - Brain Injury and Disease Prevention, Treatment and Research (Project 507) - Psychological Health and Resilience (Project 508) - Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (Project 509) Realignment eliminated certain research focus areas within Combat Casualty Care (JPC-6) and Clinical Rehabilitative Medicine (JPC-8) and reduced research in Military Operational Medicine (JPC-5). Eliminated research focus areas include: Extremity Trauma, Maxillofacial Trauma, Systems of Critical Care Delivery, Pain Management, Regenerative Medicine and Sensory Systems (Vision, Hearing and Balance).			
Accomplishments/Planned Programs Subtotals		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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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 2018	FY 2019	FY 2020
Title: Breast Cancer Center of Excellence	0.000	0.000	-
Description: Provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.			
FY 2019 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: N/A			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

C. Other Program Funding Summary (\$ in Millions)
 N/A

Remarks

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

E. Performance Metrics
 Performance 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
378B: CoE-Breast Cancer Center of Excellence (USU)	10.552	9.088	10.280	10.475	-	10.475	10.685	10.898	11.116	11.339	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 2018	FY 2019	FY 2020	
Title: Breast Cancer Center of Excellence									9.088	10.280	10.475	
Description: Breast Cancer CoE provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.												
FY 2019 Plans: 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												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 378B / <i>CoE-Breast Cancer Center of Excellence (USU)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
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 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019. FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment			
Accomplishments/Planned Programs Subtotals		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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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 2018	FY 2019	FY 2020
Title: Gynecological Cancer Center of Excellence (Army)	0.000	0.000	-
Description: The Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecological disease.			
FY 2019 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: N/A			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

C. Other Program Funding Summary (\$ in Millions)
 N/A

Remarks

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

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

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
379B: CoE-Gynecological Cancer Center of Excellence (USU)	9.226	7.943	8.987	9.158	-	9.158	9.341	9.528	9.719	9.913	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 2018	FY 2019	FY 2020	
Title: Gynecological Cancer Center of Excellence									7.943	8.987	9.158	
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 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												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 379B / <i>CoE-Gynecological Cancer Center of Excellence (USU)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
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. <i>FY 2020 Plans:</i> FY 2020 plans continue efforts as outlined in FY 2019. <i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals		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.			
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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
381A: CoE-Integrative Cardiac Health Care Center of Excellence (Army)	18.083	2.697	0.000	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 2018	FY 2019	FY 2020	
Title: Integrative Cardiac Health Center of Excellence (Army)									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 2019 Plans:												
No funding programmed. Beginning in FY19, the ICHP funding line is transferred from the Army to USUHS Project 381.												
FY 2019 to FY 2020 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									2.697	0.000	-	
C. Other Program Funding Summary (\$ in Millions)												
N/A												
Remarks												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 381A / <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i>
<u>D. Acquisition Strategy</u> 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 <u>E. Performance Metrics</u> 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.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 382A / <i>CoE-Pain Center of Excellence (Army)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
382A: <i>CoE-Pain Center of Excellence (Army)</i>	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.

<u>B. Accomplishments/Planned Programs (\$ in Millions)</u>	FY 2018	FY 2019	FY 2020
<u>Title:</u> Pain Center of Excellence (Army) <u>Description:</u> 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. <u>FY 2019 Plans:</u> No funding programmed. <u>FY 2019 to FY 2020 Increase/Decrease Statement:</u> N/A	0.000	0.000	-
Accomplishments/Planned Programs Subtotals	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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 382A / <i>CoE-Pain Center of Excellence (Army)</i>
<u>E. Performance Metrics</u> 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.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
382B: CoE-Pain Center of Excellence (USUHS)	8.079	2.822	3.310	3.376	-	3.376	3.445	3.514	3.584	3.656	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 2018	FY 2019	FY 2020	
Title: Pain Center of Excellence (USUHS)									2.822	3.310	3.376	
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 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 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.												
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.												
Accomplishments/Planned Programs Subtotals									2.822	3.310	3.376	

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 382B / <i>CoE-Pain Center of Excellence (USUHS)</i>
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.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
383A: CoE-Prostate Cancer Center of Excellence (USUHS)	41.822	7.250	8.203	8.359	-	8.359	8.526	8.696	8.870	9.047	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, NMCS, MAMC, SAMMC, and TAMC).

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2018	FY 2019	FY 2020
Title: CoE-Prostate Cancer Center of Excellence (USUHS)	7.250	8.203	8.359
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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency			Date: February 2019		
Appropriation/Budget Activity 0130 / 2		R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>		Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
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. 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.					

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency			Date: February 2019		
Appropriation/Budget Activity 0130 / 2		R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>		Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
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.					
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.					

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
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 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019. FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals		7.250	8.203
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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 398A / <i>CoE-Neuroscience Center of Excellence (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
398A: <i>CoE-Neuroscience Center of Excellence (USUHS)</i>	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 2018	FY 2019	FY 2020
Title: CoE-Neuroscience Center of Excellence (USUHS)	0.000	0.000	0.000
Description: The Military Clinical Neuroscience Center of Excellence (MCNCoE) is to improve prevention, diagnosis, and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions. The MCNCoE's approach to its goals includes supporting the research potential of military treatment facilities across the DOD system as well as the national capital area, and facilitating a network of collaborations between investigators across these facilities.			
FY 2019 Plans:			
FY 2020 Plans:			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary (\$ in Millions)
N/A

Remarks

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 398A / <i>CoE-Neuroscience Center of Excellence (USUHS)</i>
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	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 2018	FY 2019	FY 2020
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 2019 Plans: No funding programmed. FY 2019 to FY 2020 Increase/Decrease Statement: N/A										0.000	0.000	-
Accomplishments/Planned Programs Subtotals										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.												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
431A: Underbody Blast Testing (Army)	40.611	8.000	10.800	9.200	-	9.200	1.400	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

To better protect mounted warriors from the effects of underbody blast (UBB) caused by landmines or Improvised Explosive Devices (IEDs), 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 2018	FY 2019	FY 2020
Title: Underbody Blast Testing	8.000	10.800	9.200
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 2019 Plans: Biofidelity response corridors will be used to validate second generation prototypes of the WIAMan. Human injury assessment curves will continue to be developed for the lower extremities, pelvis and spine from laboratory testing that created thresholds of cadaveric fractures and subsequent severe injuries (i.e., complex fractures). Laboratory testing to generate female post mortem human subject injury tolerances will continue and will be used to inform the analysis of alternatives for developing a female specific manikin.			
FY 2020 Plans: Human Injury Probability Curves, Injury Assessment Reference Curves, and Female cadaver testing will be completed and the WIMAN research team will report on ways to account for female skeletal properties in the ATD. WIAMan Post-Mortem			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 431A / <i>Underbody Blast Testing (Army)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
Human Subject data will be cataloged and stored at the Army Research Lab Engineering Analysis Branch (EAB) for Verification, Validation and Accreditation activities for Live Fire vehicle testing. Data sharing will be coordinated with medical research labs.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing adjustment.			
Accomplishments/Planned Programs Subtotals		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 Principal Investigators (PIs) will participate in In-Progress Reviews, technical interchange meetings, and theater injury analysis reviews. PIs will publish emerging results in the Proceedings of Injury Biomechanics Symposia and in relevant journals. As required, PIs will participate in DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and are subjected to 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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
448A: Military HIV Research Program (Army)	25.095	6.359	7.360	7.877	-	7.877	8.035	8.196	8.361	8.528	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 2018	FY 2019	FY 2020
Title: Military HIV Research Program	6.359	7.360	7.877
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 2019 Plans: The Military HIV research program is conducting 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. Human population studies in Asia, Europe and West Africa are being conducted to provide knowledge about the earliest HIV events to inform vaccine development. Human clinical trials in Africa, Asia and the U.S. designed to test for safety, immunogenicity and early proof of concept efficacy of candidate vaccines are ongoing. FY 2020 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 448A / <i>Military HIV Research Program (Army)</i>		
B. Accomplishments/Planned Programs (\$ in Millions) FY 2020 plans continue efforts as outlined in FY 2019. <i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Pricing adjustment.		FY 2018	FY 2019	FY 2020
Accomplishments/Planned Programs Subtotals		6.359	7.360	7.877
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.				

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
830A: Deployed Warfighter Protection (Army)	28.983	5.123	5.930	6.345	-	6.345	6.473	6.601	6.733	6.868	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 2018	FY 2019	FY 2020	
Title: Deployed Warfighter Protection									5.123	5.930	6.345	
Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects.												
FY 2019 Plans: The Deployed Warfighter Protection research project continues to conduct 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 AFPMB Vector Control Capabilities Gap Analysis (completed in FY 2016) will continue to be used to inform the development of functional and performance requirements for future acquisition programs. In addition, the AFPMB continues to develop the necessary test and evaluation plans to determine a candidate product's ability to meet its stated requirements..												
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.												
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing adjustment.												
Accomplishments/Planned Programs Subtotals									5.123	5.930	6.345	
C. Other Program Funding Summary (\$ in Millions)												
N/A												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 830A / <i>Deployed Warfighter Protection (Army)</i>
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 Deployed Warfighter Protection program is measured by the insecticides and other products given EPA registration and added to the military stock system, changes in pest management techniques or technologies used by the military to control biting/disease causing insects, patents, and peer-reviewed scientific manuscripts. The Program conducts an annual Research Review during which a panel of DoD subject matter experts provides input on programmatic alignment and strategic priorities.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
478: Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)	0.000	14.766	14.754	18.556	-	18.556	18.639	18.724	19.098	19.480	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 ASDMs. 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 ASDMs 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 2018	FY 2019	FY 2020
Title: DoD Cancer Moonshot - Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)	14.766	14.754	18.556
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			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 478 / <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		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 2019 Plans: APOLLO - FY 2019 plans continue efforts as outlined in FY 2018 to collect 1,000 cancer specimens (all cancer types) and run them through 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. In addition, identify Framingham 3 serum specimens and run them through the serum protein analysis lab platform, and perform initial data analytics on the results. FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019. FY 2019 to FY 2020 Increase/Decrease Statement: Previous years reflect program start-up, FY 2020 and out reflect full funding.			
Accomplishments/Planned Programs Subtotals		14.766	14.754
C. Other Program Funding Summary (\$ in Millions)			
N/A			
Remarks			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 478 / <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i>
<u>D. Acquisition Strategy</u> N/A		
<u>E. Performance Metrics</u> To be determined.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
479: Framingham Longitudinal Study (USUHS)	0.000	4.920	4.920	4.920	-	4.920	4.920	4.920	5.018	5.118	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 ASDMs. 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 ASDMs 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 2018	FY 2019	FY 2020
Title: DoD Cancer Moonshot Program - DoD Framingham Longitudinal Study	4.920	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 ASDMs 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 ASDMs 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			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 479 / <i>Framingham Longitudinal Study (USUHS)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		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 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. FY 2020 Plans: Continue to identify Framingham serum specimens and conduct serum protein analysis lab platform, and perform initial data analytics on the results.			
Accomplishments/Planned Programs Subtotals		4.920	4.920
C. Other Program Funding Summary (\$ in Millions)			
N/A			
Remarks			
D. Acquisition Strategy			
N/A			
E. Performance Metrics			
Performance Metrics to be determined.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
499: MHS Financial System Acquisition	1.766	13.456	21.129	15.373	-	15.373	1.971	2.011	2.051	2.092	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 2018	FY 2019	FY 2020	
Title: MHS Financial System Acquisition									13.456	21.129	15.373	
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 2019 Plans: FY 2019 plans continue efforts as outlined in FY 2018.												
FY 2020 Plans:												
FY 2019 to FY 2020 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									13.456	21.129	15.373	
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost	
• BA 3: PE 0807721 Replacement & Modernization	9.031	10.409	22.611	-	22.611	0.000	0.000	0.000	-	Continuing	Continuing	

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2				R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 499 / <i>MHS Financial System Acquisition</i>				
C. Other Program Funding Summary (\$ in Millions)												
	<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
Remarks												
D. Acquisition Strategy												
Acquisition Strategy is to be determined.												
E. Performance Metrics												
Performance metrics to be determined.												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
381: CoE - Integrative Cardiac Health Care (USUHS)	0.000	0.000	2.914	3.118	-	3.118	3.180	3.244	3.309	3.375	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 2018	FY 2019	FY 2020	
Title: Integrative Cardiac Health Center of Excellence									0.000	2.914	3.118	
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 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 designed to significantly advance the precision of risk detection and lead to an improvement of current interventions and patient outcomes.												
FY 2020 Plans:												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 381 / <i>CoE - Integrative Cardiac Health Care (USUHS)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals		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.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
504: WRAIR Vaccine Production Facility Research	0.000	0.000	8.000	8.152	-	8.152	8.315	8.481	8.651	8.824	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 2018	FY 2019	FY 2020	
Title: WRAIR Vaccine Production Facility									-	8.000	8.152	
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 2020 Plans: The WRAIR PBF program will continue vaccine and biologic production efforts for use in early phase clinical trials to assess safety and effectiveness of candidate vaccines.												
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing adjustment.												
Accomplishments/Planned Programs Subtotals									-	8.000	8.152	
C. Other Program Funding Summary (\$ in Millions)												
N/A												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 504 / <i>WRAIR Vaccine Production Facility Research</i>
C. Other Program Funding Summary (\$ in Millions)		
Remarks		
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 viald, 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.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 506 / Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
506: Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)	-	0.000	0.000	11.904	-	11.904	12.141	12.385	12.631	12.883	Continuing	Continuing

A. Mission Description and Budget Item Justification

The “Health Research for Improved Medical Readiness and Healthcare Delivery” program at USUHS is to answer fundamental questions of importance to the military mission of the Department of Defense in five (5) distinct portfolio areas: health services research, global health engagement, precision medicine, women’s health, and infectious disease clinical research.

B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020
Title: Health Research for Improved Medical Readiness and Healthcare Delivery									0.000	0.000	11.904
Description: The objective of Health Services Research is to build capacity to conduct health services research (HSR) within the MHS. The program will address the lack of system-wide health care evidence to support policy and decision making and insufficient health services research capability to analyze MHS data for improving medical readiness and efficient, effective, quality and safe healthcare.											
Global Health Engagement (GHE) research is related to operational efforts and advanced technology development efforts that will meet the needs of the Joint Force in either improving the understanding and/or execution of DoD GHE, or utilizing DoD health research activities to engage a partner nation/partner nations in support of Theater Campaign Plan objectives to further research. The GHE research needs of the warfighter are expressed by the regular demand signal of the Joint Force through the Joint Staff Surgeon’s Office and the Combatant Commands Surgeons’ Offices.											
Precision Medicine will provide standardized genome profiling services across the MHS. It will provide genomic data analysis and storage under DoD security and privacy compliance policies in order to provide cutting edge genomic information to clinicians and improve health care of warfighter.											
The military Women's Health research program mission is to develop and guide best practices for the clinical care of women in the military system, through medical research. This research program will identify priorities that utilize novel and well-defined methods in the areas of personalized medicine and population science and focuses on basic, clinical and translational research.											

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 506 / <i>Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
Infectious Disease Clinical Research is multicenter infectious diseases clinical research focusing on high-impact cohorts and interventional trials, to inform and improve care of the Warfighter. The focus is on emerging infections, antimicrobial resistance, and other high priority infections impacting military readiness in US and abroad. It also will generate research evidence to inform warfighter care, develop DoD clinical practice guidance, assess cost effectiveness of interventions, and assist force health protection policy development. FY 2019 Plans: Funding for this program is being executed by MRMC in FY19. FY 2020 Plans: Health Services Research: - Define research priorities: Health economics, geographic variation, provider induced demand, disparities, improving care to populations of patients, outcome studies, program evaluation. - Improve policy and practice in the MHS through knowledge translation. Global Health Engagement: - Improve the efficacy of military medical engagements with partner nations in achieving military outcomes - Improve the readiness of the Joint Force to conduct GHE activities in support of Geographic Combatant Commands and national security objectives - Improve the quality of tools and capabilities available to commanders for conducting international security cooperation and cooperative health security engagements Precision Medicine: - Enable single collection site of genomic data for DoD Precision Medicine studies to contribute towards population medicine innovation. - Improve utility for supercomputing infrastructure supporting clinical activities. Women's Health research: - Support research projects in the areas of reproductive health, pain, mental health, cardiovascular disease, cancer, human performance and readiness standards, nutrient and energy requirements for servicewomen, medical simulation violence against women, opioid use and, clinical practice guidelines. Infectious Disease Research:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 506 / <i>Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)</i>	

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
- Execute multisite research through a robust sustainable MHS research network, with capability to execute FDA-regulated clinical trials. - Translate generated high quality evidence as follows: Develop new and refined DoD clinical practice guidance in support of Force Health Protection, inform DoD and National policies related to the prevention and management of infectious diseases, and provide direct support of infection threat assessment and mitigation efforts to the Geographic Combatant Commands in collaboration with Military Public Health authorities. FY 2019 to FY 2020 Increase/Decrease Statement: Funding increase is the result of a realignment of funds in FY 2020 from MRMC to USUHS in FY 2020 for health services research, global health engagement, precision medicine, women's health and infectious disease clinical research.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	11.904

	FY 2018	FY 2019
Congressional Add:	0.000	-
FY 2018 Accomplishments:		
Congressional Adds Subtotals	0.000	-

C. Other Program Funding Summary (\$ in Millions)
 N/A

Remarks

D. Acquisition Strategy
 N/A

E. Performance Metrics
 N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 507 / Brain Injury and Disease Prevention, Treatment and Research (USUHS)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
507: Brain Injury and Disease Prevention, Treatment and Research (USUHS)	-	0.000	0.000	13.317	-	13.317	13.583	13.855	14.132	14.415	Continuing	Continuing
A. Mission Description and Budget Item Justification This program supports drug discovery for chronic traumatic and encephalopathy/neurodegenerative disease.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Brain Injury and Disease Prevention, Treatment and Research									0.000	0.000	13.317	
Description: Brain Injury and Disease Prevention, Treatment and Research is focused upon identifying drugs that will interfere with pathological tau prion formation in the brains of service members who are at risk for developing CTE and other neurodegenerative diseases following repeated TBI. Service members who have served in combat and have received repeated impact and/or blast TBIs are at risk for developing chronic traumatic encephalopathy (CTE) and other neurodegenerative diseases which are associated with significant persistent behavioral/neurologic manifestations. Currently, there are no validated means for diagnosing these problems in living patients or drugs to effectively treat them. The overall mission of this program is to develop drug candidates that will effectively block the formation of brain tau prions that can be entered into clinical trials for the prevention and/or treatment of CTE and other neurodegenerative disorders in at-risk active duty and retired service members.												
FY 2019 Plans: None												
FY 2020 Plans: The USUHS plans for FY 2020 are to: - Screen for drug candidates that interfere with brain tau prion formation, a defining feature of CTE and other neurodegenerative diseases and maximize their bioavailability and therapeutic effectiveness. - Identify compounds that will enter the brain and bind with aggregated tau prions and can be used as PET tracers for diagnosis and markers of disease progression. - Develop animal models of tau prion formation to test efficacy of putative drug candidates - Using candidate drugs identified under this program, prepare to initiate clinical trials in at-risk service members for the treatment or prevention of CTE and other tau prion-related disorders.												
FY 2019 to FY 2020 Increase/Decrease Statement:												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 507 / <i>Brain Injury and Disease Prevention, Treatment and Research (USUHS)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
Funds increase is the result of a baseline realignment of funds in from GDF starting in FY 2020 for brain injury and disease prevention, treatment, and research.			
Accomplishments/Planned Programs Subtotals		0.000	0.000
		13.317	
C. Other Program Funding Summary (\$ in Millions)			
N/A			
Remarks			
D. Acquisition Strategy			
N/A			
E. Performance Metrics			
N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 508 / Psychological Health and Resilience (USUHS)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
508: Psychological Health and Resilience (USUHS)	-	0.000	0.000	7.000	-	7.000	7.140	7.283	7.428	7.577	Continuing	Continuing
A. Mission Description and Budget Item Justification												
The “Psychological Health and Resilience” program at USUHS is designed to answer fundamental questions of importance to the military medical mission of the Department of Defense in the areas of prevention, treatment and recovery of warfighters and families in behavioral and mental health, which are critical to force health and readiness. Research is necessary to guide policy and ensure optimal delivery of behavioral health training and services across the continuum of care and deployment cycle. Threats addressed by this research component include post-traumatic stress disorder (PTSD), suicide, family separation, and family violence.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title:									0.000	0.000	7.000	
Description: STARRS-LS, the longitudinal successor to the groundbreaking Army STARRS research conducted from 2009 to 2015, is the largest study of military suicide ever undertaken, and in addition has yielded a wealth of information about a variety of other health issues relevant to the military. STARRS-LS seeks to extend the original effort by continuing to follow the original participants, expanding the Historical Administrative Data Study and using Big Data techniques to develop knowledge from it, and by combining survey and health outcome data with genetic analyses from samples provided by research participants.												
FY 2019 Plans:												
None												
FY 2020 Plans:												
- Maintaining the current data and biospecimens for future analyses -- Historical Administrative Data Study (HADS), survey data, and biorepository.												
- Conduct future wave of data collection from original STARRS-LS Army sample and link to historical data records.												
- Develop prediction algorithms for suicide attempts and other outcomes.												
- Provide the resultant knowledge to the Army and DoD for use in modifying recruitment algorithms and developing targeted early preventive intervention programs for Soldiers at high risk of adverse outcomes.												
FY 2019 to FY 2020 Increase/Decrease Statement:												
Funds increase is the result of a baseline realignment of funds in from GDF starting in FY 2020 for Psychological Health and Resilience programs.												
Accomplishments/Planned Programs Subtotals									0.000	0.000	7.000	

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 508 / <i>Psychological Health and Resilience (USUHS)</i>
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 509 / Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
509: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)	-	0.000	0.000	19.323	-	19.323	19.710	20.104	20.505	20.916	Continuing	Continuing

A. Mission Description and Budget Item Justification

The “Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness” program at USUHS is designed to answer fundamental questions of importance to the military medical mission of the Department of Defense in the three portfolio areas: Transforming Technology for the Warfighter (TTW), Surgical Critical Care, and the Rehabilitation Sciences Research.

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Title: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness Description: The TTW program aims to support highly collaborative advanced technology projects by bringing together industry, academia and civilian medical centers including minority serving institutions with experience in solving defense and civilian health problems. Supported projects will focus on the 3 principal medical areas for defense health (Combat Casualty Care, Military Operational Medicine, and Clinical and Rehabilitative Medicine) with an emphasis on direct relevance to identified military needs, translational potential and clear strategy for product commercialization with a low to medium risk – high reward payoff. Additionally, for USU, the TTW program will cultivate, establish and leverage partnerships between USU faculty/investigators and industry, academia and civilian medical centers including minority serving institutions. Results from the TTW program will increase DoD’s workforce capability, DoD’s access to leading edge technologies and leverage industry knowledge and funded research data for warfighter medical needs. Surgical Critical Care (SC2i) will enroll critically ill patients, leveraging deep medical and –omics data to develop Clinical Decision Support Tools (CDSTs) that will improve clinical outcomes and lower resource utilization across military and civilian healthcare systems. The CDSTs will further assist readiness by either accelerating return to duty (abridged length-of-stay across the ICU, general ward, and rehabilitation continuum of care) and curbing medical resource burdens. Rehabilitation Sciences Research supports clinical and translational research efforts dedicated to enhancing the rehabilitative care of the wounded warrior, particularly those with orthopeadic trauma, amputation and neurological injury. Research focus areas include: 1)Identifying and mitigating barriers to successful rehabilitation, return to duty and community reintegration; 2) Improved pain management to support active participation in rehabilitation; 3) Applying Advanced Technologies to augment	0.000	0.000	19.323

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 509 / <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
rehabilitation methods and outcomes assessments; 4) Developing and testing advanced technologies to restore individual functional independence; 5) Regenerative Rehabilitation translational products for war-related trauma. FY 2019 Plans: None FY 2020 Plans: Transforming Technology for the Warfighter: - Support the advancement of medical technologies such as 1) wearable devices (e.g. enhanced performance monitoring using biosensors), 2) operational injuries (e.g. TBI, blast injuries, trauma care), 3) rehabilitation (e.g. regenerative medicine, wound healing), 4) precision medicine (e.g. omics, biomarkers), and 5) rapid treatment and diagnostics at point of injury. - Cultivate, establish and leverage partnerships with industry, academia and civilian medical centers including minority serving institutions to create, innovate and advance disruptive medical technologies to address warfighter medical needs. Surgical Critical Care: - SC2i will leverage a databank to develop, validate, and/or deploy eleven (11) predictive algorithms for conditions associated with high mortality and morbidity (e.g. timing of closure of extremity and open abdominal injuries, venous thromboembolism, pneumonia, bacteremia, acute kidney injury, acute respiratory distress syndrome, heterotopic ossification, small bowel obstruction, acute appendicitis, and vasospasm for severe traumatic brain injuries). - It will support robust medical education and training to ensure the battlefield surgeons of tomorrow are appropriately trained in the use of clinical and biomarker-based CDSTs. Rehabilitation Sciences Research: - Define the optimal rehabilitation strategies and prosthetic selection, fitting and training for wounded warriors with osseointegration (direct skeletal attachment of a prosthesis) - Examine the clinical efficacy of virtual and augmented reality applications to enhance rehabilitation of individuals with extremity dysfunction and acquired brain injury. - Develop clinical applicable tools to objectively assess gait for individuals with lower limb amputation and dysfunction - Explore potential rehabilitative interventions to mitigate heterotopic ossification formation from blast thru translatable model - Understand the bio-psycho-social and genetic factors that influence symptomatology and response to novel treatments for individuals with TBI, Amputation, and PTSD, including phantom limb pain, secondary back pain, and post-concussive symptoms. FY 2019 to FY 2020 Increase/Decrease Statement:			
		FY 2020	

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 509 / <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
Funds increase is the result of a baseline realignment of funds in from GDF in FY 2020 for Transforming Technologies for the Warfighter, Surgical Critical Care, and Rehabilitation Sciences Research.			
Accomplishments/Planned Programs Subtotals		0.000	19.323
	FY 2018	FY 2019	
Congressional Add:	0.000	-	
FY 2018 Accomplishments:			
Congressional Adds Subtotals	0.000	-	
C. Other Program Funding Summary (\$ in Millions)			
N/A			
Remarks			
D. Acquisition Strategy			
N/A			
E. Performance Metrics			
N/A			