Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Defense Health Agency											Date: April 2022	
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 2021**	**FY 2022**	**FY 2023 Base**	**FY 2023 OCO**	**FY 2023 Total**	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**	**Cost To Complete**	**Total Cost**
Total Program Element	9,798.546	1,994.150	2,008.177	320.496	0.000	320.496	326.420	328.099	332.660	338.070	Continuing	Continuing
300A: *CSI - Congressional Special Interests*	8,849.659	1,763.897	1,772.980	0.000	0.000	0.000	0.000	0.000	0.000	0.000	-	-
238C: *Air & Space Austere Environment Patient Care and Transport (AF)*	14.921	11.250	12.675	12.866	0.000	12.866	13.122	13.386	13.653	13.927	Continuing	Continuing
284B: *Air & Space Physiology, Medicine and Human Performance (AF)*	11.156	10.418	11.122	11.471	0.000	11.471	11.700	11.933	12.172	12.415	Continuing	Continuing
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	17.469	0.232	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
307B: *Air & Space Force Health Protection (AF)*	29.148	10.046	11.463	11.630	0.000	11.630	11.862	12.098	12.340	12.586	Continuing	Continuing
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	21.391	2.623	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
309A: *Regenerative Medicine (USUHS)*	25.909	10.413	10.621	10.833	0.000	10.833	11.051	11.271	11.496	11.724	Continuing	Continuing
373: *GDF - Medical Technology Development*	401.932	5.001	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
373A: *GDF - MTD (Combat Casualty Care)*	0.000	11.168	15.736	24.519	0.000	24.519	26.943	27.950	28.871	29.810	Continuing	Continuing
373B: *GDF - MTD (Military Operational Medicine)*	0.000	23.255	19.046	34.150	0.000	34.150	32.426	33.152	33.815	34.492	Continuing	Continuing
373C: *GDF - MTD (Medical Simulation & Training/Health Informatics)*	0.000	12.613	13.044	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
373D: *GDF - MTD (Clinical and Rehabilitation Medicine)*	0.000	13.040	14.980	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Defense Health Agency										Date: April 2022		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115DHA *I Medical Technology Development*							
373E: *GDF - MTD (Military Infectious Disease)*	0.000	6.409	6.630	12.886	0.000	12.886	13.817	13.747	13.659	13.570	Continuing	Continuing
373F: *GDF - MTD (Radiological Health Effects)*	0.000	0.501	0.518	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
373G: *GDF - MTD (Military Medical Photonics)*	0.000	10.000	10.200	10.404	0.000	10.404	10.612	10.824	11.040	11.261	Continuing	Continuing
373H: *GDF - MTD (Medical Advanced Technology)*	0.000	0.000	0.000	68.016	0.000	68.016	68.576	64.720	63.969	63.969	Continuing	Continuing
378B: *CoE-Breast Cancer Center of Excellence (USUHS))*	29.843	10.685	10.898	11.116	0.000	11.116	11.339	11.566	11.797	12.033	Continuing	Continuing
379B: *CoE-Gynecological Cancer Center of Excellence (USUHS)*	26.088	9.341	9.528	9.719	0.000	9.719	9.913	10.111	10.313	10.519	Continuing	Continuing
381: *CoE - Integrative Cardiac Health Care (USUHS)*	5.929	1.680	1.744	1.809	0.000	1.809	1.875	1.943	1.982	2.022	Continuing	Continuing
382B: *CoE-Pain Center of Excellence (USUHS)*	9.508	1.945	2.014	2.084	0.000	2.084	2.156	2.230	2.277	2.327	Continuing	Continuing
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	23.812	8.526	8.696	8.870	0.000	8.870	9.047	9.228	9.413	9.600	Continuing	Continuing
431A: *Underbody Blast Testing (Army)*	68.611	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	-	-
448A: *Military HIV Research Program (Army)*	46.516	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
478: *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*	48.076	18.640	18.724	19.058	0.000	19.058	19.480	19.870	20.267	20.672	Continuing	Continuing
479: *Framingham Longitudinal Study (USUHS)*	14.760	4.920	4.920	5.018	0.000	5.018	5.118	5.220	5.324	5.430	Continuing	Continuing
499: *MHS Financial System Acquisition (DHA)*	39.958	1.971	6.011	6.051	0.000	6.051	6.092	6.143	6.266	6.388	Continuing	Continuing

Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Defense Health Agency										Date: April 2022		
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0603115DHA *I Medical Technology Development*							
504: *WRAIR Vaccine Production Facility Research (Army)*	16.152	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
506: *Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)*	11.904	11.141	11.385	11.631	0.000	11.631	11.883	12.141	12.384	12.632	Continuing	Continuing
507: *Brain Injury and Disease Prevention, Treatment and Research (USUHS)*	13.317	13.583	13.855	14.132	0.000	14.132	14.415	14.703	14.997	15.297	Continuing	Continuing
508: *Psychological Health and Resilience (USUHS)*	7.000	7.140	7.283	7.428	0.000	7.428	7.577	7.729	7.884	8.042	Continuing	Continuing
509: *Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)*	19.323	13.712	14.104	14.505	0.000	14.505	14.916	15.334	15.641	15.954	Continuing	Continuing
511: *Cancer Moonshot Initiatives*	0.000	0.000	0.000	12.300	0.000	12.300	12.500	12.800	13.100	13.400	Continuing	Continuing
830A: *Deployed Warfighter Protection (Army)*	46.164	0.000	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

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 National Defense Strategy, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, and the National Biodefense Strategy.

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 and the Department of Health and Human Services. 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.

Three Centers of Excellence (CoEs) 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 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.

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.

Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Defense Health Agency	Date: April 2022
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603115DHA *I Medical Technology Development*

B. Program Change Summary ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Previous President's Budget	1,994.150	235.197	320.496	0.000	320.496
Current President's Budget	1,994.150	2,008.177	320.496	0.000	320.496
Total Adjustments	0.000	1,772.980	0.000	0.000	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	1,772.980			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2021	FY 2022
Project: 300A: *CSI - Congressional Special Interests*		
Congressional Add: *245A - Amyotrophic Lateral Sclerosis (ALS) Research*	40.000	40.000
Congressional Add: *293A - Autism Research*	15.000	15.000
Congressional Add: *296A - Bone Marrow Failure Disease Research*	7.500	7.500
Congressional Add: *310A - Peer-Reviewed Ovarian Cancer Research*	35.000	45.000
Congressional Add: *328A - Peer- Reviewed Multiple Sclerosis Research*	20.000	20.000
Congressional Add: *335A - Peer-Reviewed Cancer Research*	115.000	130.000
Congressional Add: *336A - Peer-Reviewed Lung Cancer Research*	20.000	20.000
Congressional Add: *337A - Peer-Reviewed Orthopaedic Research*	30.000	30.000
Congressional Add: *338A - Peer-Reviewed Spinal Cord Research*	40.000	40.000
Congressional Add: *339A - Peer-Reviewed Vision Research*	20.000	20.000
Congressional Add: *352A - Traumatic Brain Injury/Psychological Health Research*	175.000	175.000
Congressional Add: *380A - Peer-Reviewed Breast Cancer Research*	150.000	150.000
Congressional Add: *390A - Peer-Reviewed Prostate Cancer Research*	110.000	110.000
Congressional Add: *392A - Gulf War Illness Peer-Reviewed Research*	22.000	0.000
Congressional Add: *396A - Research in Alcohol and Substance Use Disorders*	4.000	4.000
Congressional Add: *400A - Peer-Reviewed Medical Research*	370.000	370.000
Congressional Add: *417A - Peer-Reviewed Alzheimer Research*	15.000	15.000

Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Defense Health Agency	Date: April 2022
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603115DHA *I Medical Technology Development*

Congressional Add Details ($ in Millions, and Includes General Reductions)	**FY 2021**	**FY 2022**
Congressional Add: *439A - Joint Warfighter Medical Research*	32.000	24.000
Congressional Add: *452A - Peer-Reviewed Reconstructive Transplant Research*	12.000	12.000
Congressional Add: *454A - Orthotics and Prosthetics Outcomes Research*	15.000	20.000
Congressional Add: *456A - HIV/AIDS Program*	16.000	18.000
Congressional Add: *459A - Peer-Reviewed Epilepsy Research*	12.000	12.000
Congressional Add: *463A – Program Increase: Restore Core Research Funding Reduction (GDF)*	221.215	212.980
Congressional Add: *495 - Peer-Reviewed Tick-Borne Disease Research*	7.000	7.000
Congressional Add: *496 -Trauma Clinical Research Program*	10.000	10.000
Congressional Add: *501 - Peer-Reviewed Hearing Restoration Research (Army)*	10.000	10.000
Congressional Add: *502 - CSI - Peer-Reviewed Kidney Cancer Research (Army)*	50.000	50.000
Congressional Add: *503 - CSI - Peer-Reviewed Lupus Research (Army)*	10.000	10.000
Congressional Add: *540A - Global HIV/AIDS Prevention (Navy)*	8.000	10.000
Congressional Add: *660A - Tuberous Sclerosis Complex (TSC)*	8.000	8.000
Congressional Add: *790A - Peer-Reviewed Duchenne Muscular Dystrophy*	10.000	10.000
Congressional Add: *512 - Peer-Reviewed Melanoma Research*	30.000	40.000
Congressional Add: *513 - Chronic Pain Management*	15.000	15.000
Congressional Add: *514 - Combat Readiness Medical Research*	10.000	10.000
Congressional Add: *515 - Peer-Reviewed Pancreatic Cancer Research*	15.000	15.000
Congressional Add: *516 - Peer-Reviewed Rare Cancers Research*	17.500	17.500
Congressional Add: *517 - Peer-Reviewed Scleroderma Research*	5.000	0.000
Congressional Add: *300A - Congressional Add - Brain injury and disease prevention research*	61.682	60.000
Congressional Add: *300A - Congressional Add - Clinical research*	-	10.000
Congressional Add Subtotals for Project: 300A	1,763.897	1,772.980
Project: 373H: *GDF - MTD (Medical Advanced Technology)*		
Congressional Add: *N/A*	0.000	0.000
Congressional Add Subtotals for Project: 373H	0.000	0.000

Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Defense Health Agency	Date: April 2022
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0603115DHA *I Medical Technology Development*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2021	FY 2022
Project: 511: *Cancer Moonshot Initiatives*		
Congressional Add: *Cancer Moonshot Initiatives (USUHS)*	0.000	0.000
Congressional Add Subtotals for Project: 511	0.000	0.000
Congressional Add Totals for all Projects	1,763.897	1,772.980

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
300A: *CSI - Congressional Special Interests*	8,849.659	1,763.897	1,772.980	0.000	0.000	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

In FY 2022, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2022 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 2021	FY 2022
Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research	40.000	40.000
FY 2021 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		
FY 2022 Plans: 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		
Congressional Add: 293A - Autism Research	15.000	15.000
FY 2021 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.		
FY 2022 Plans: 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.		
Congressional Add: 296A - Bone Marrow Failure Disease Research	7.500	7.500

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
FY 2021 Accomplishments: This Congressional Special Interest initiative provided funds for bone marrow failure diseases research. The mission of the Bone Marrow Failure Research Program is to sponsor innovative research that will advance the understanding of inherited and acquired bone marrow failure diseases, and improve the health and life of individuals living with these diseases, with the ultimate goal of prevention and/or cure. This effort has solicited research proposals focused on bone marrow failure syndromes and their long-term effects from the basic science and clinical research sectors. ***FY 2022 Plans:*** 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.		
Congressional Add: 310A - Peer-Reviewed Ovarian Cancer Research ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for ovarian cancer research. In striving to achieve the goal of eliminating ovarian cancer, the Ovarian Cancer Research Program (OCRP) challenges the research community to address high impact, innovative research. The FY 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. ***FY 2022 Plans:*** 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.	35.000	45.000
Congressional Add: 328A - Peer- Reviewed Multiple Sclerosis Research ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for Multiple Sclerosis (MS) research. The mission of the Multiple Sclerosis Research Program (MSRP) is to support pioneering	20.000	20.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
concepts and high-impact research relevant to the prevention, etiology, pathogenesis, assessment, and treatment of MS. ***FY 2022 Plans:*** 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.		
Congressional Add: 335A - Peer-Reviewed Cancer Research ***FY 2021 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. ***FY 2022 Plans:*** 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.	115.000	130.000
Congressional Add: 336A - Peer-Reviewed Lung Cancer Research ***FY 2021 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. ***FY 2022 Plans:*** 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.	20.000	20.000
Congressional Add: 337A - Peer-Reviewed Orthopaedic Research	30.000	30.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
FY 2021 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 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. ***FY 2022 Plans:*** 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 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.		
Congressional Add: 338A - Peer-Reviewed Spinal Cord Research ***FY 2021 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. ***FY 2022 Plans:*** 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.	40.000	40.000
Congressional Add: 339A - Peer-Reviewed Vision Research ***FY 2021 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	20.000	20.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
maintenance of visual function to ensure and sustain combat readiness and directly benefit the lives of military, Veteran, and civilian populations. ***FY 2022 Plans:*** 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.		
Congressional Add: 352A - Traumatic Brain Injury/Psychological Health Research ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for research aimed to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and combat-related traumatic brain injury (TBI) on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, Veterans, family members, caregivers, and communities. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for research aimed to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and combat-related traumatic brain injury (TBI) on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, Veterans, family members, caregivers, and communities.	175.000	175.000
Congressional Add: 380A - Peer-Reviewed Breast Cancer Research ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for breast cancer research. The Breast Cancer Research Program challenged the scientific community to design research that addresses the urgency of ending breast cancer. Applications were required to address at least one of nine overarching challenges, which were focused on preventing breast cancer, identifying determinants of breast cancer initiation, risk, or susceptibility, distinguishing deadly from non-deadly breast cancers, conquering the problems of over-diagnosis and over-treatment, identifying what drives breast cancer growth and determining how to stop it, identifying why some breast cancers become metastatic, determining how to prevent recurrence, revolutionizing treatment regimens by replacing them with ones that are more effective, less toxic, and impact survival, and eliminating the mortality associated with metastatic breast cancer. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for breast cancer research. The Breast Cancer Research Program challenged the scientific community to design research that addresses the urgency of ending breast cancer. Applications were required to address at least one of nine overarching	150.000	150.000

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Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
challenges, which were focused on preventing breast cancer, identifying determinants of breast cancer initiation, risk, or susceptibility, distinguishing deadly from non-deadly breast cancers, conquering the problems of over-diagnosis and over-treatment, identifying what drives breast cancer growth and determining how to stop it, identifying why some breast cancers become metastatic, determining how to prevent recurrence, revolutionizing treatment regimens by replacing them with ones that are more effective, less toxic, and impact survival, and eliminating the mortality associated with metastatic breast cancer.		
Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research	110.000	110.000
FY 2021 Accomplishments: This Congressional Special Interest initiative provided funds for prostate cancer research. The vision for the 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. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for prostate cancer research. The vision for the 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.		
Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research	22.000	0.000

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Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
FY 2021 Accomplishments: This Congressional Special Interest initiative provided funds for Gulf War Illness research. The vision for the Gulf War Illness Research Program was improving the health and lives of Veterans who have Gulf War Illness by funding research to identify effective treatments, improve clinical definition and diagnosis, and to better understand the underlying biology and symptoms of Gulf War Illness. ***FY 2022 Plans:*** N/A		
Congressional Add: 396A - Research in Alcohol and Substance Use Disorders ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for alcohol and substance use disorders (ASUD) research. The goal of the 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). ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for alcohol and substance use disorders (ASUD) research. The goal of the 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).	4.000	4.000
Congressional Add: 400A - Peer-Reviewed Medical Research ***FY 2021 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 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,	370.000	370.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
Tuberculosis, Vaccine Development for Infectious Diseases, Vascular Malformations, and Women's Heart Disease. ***FY 2022 Plans:*** 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 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 Disease.		
Congressional Add: 417A - Peer-Reviewed Alzheimer Research ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for Alzheimer's disease (AD) research. The FY 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. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for Alzheimer's disease (AD) research. The 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.	15.000	15.000
Congressional Add: 439A - Joint Warfighter Medical Research ***FY 2021 Accomplishments:*** The FY 2018 Joint Warfighter Medical Research Program (JWMRP) provides continuing support for promising projects previously funded by Congressional Special Interest initiatives. The	32.000	24.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
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. ***FY 2022 Plans:*** 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.		
Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for reconstructive transplantation research. The Reconstructive Transplant Research Program (RTRP) focused on research in reconstructive transplantation for the refinement of approaches for hand, face, and other vascularized composite tissue allografts, which includes multiple body system components such as skin, muscle, tendon, nerves, bone, and blood vessels. In addition, the RTRP focused on research aimed toward improving access to reconstructive transplants, and on immunomodulation strategies that can reduce the need for immunosuppression regimens. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for reconstructive transplantation research. The FY 2018 Reconstructive Transplant Research Program (RTRP) focused on research in reconstructive transplantation for the refinement of approaches for hand, face, and other vascularized composite tissue allografts, which includes multiple body system components such as skin, muscle, tendon, nerves, bone, and blood vessels. In addition, the RTRP focused on research aimed toward improving access to reconstructive transplants, and on immunomodulation strategies that can reduce the need for immunosuppression regimens.	12.000	12.000
Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research ***FY 2021 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. ***FY 2022 Plans:*** 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	15.000	20.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
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.		
Congressional Add: 456A - HIV/AIDS Program ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for HIV/AIDS research includes all medical research that attempts to prevent, treat, or cure HIV/AIDS, as well as fundamental research about the nature of HIV as an infectious agent and AIDS as the disease caused by HIV. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for HIV/AIDS research includes all medical research that attempts to prevent, treat, or cure HIV/AIDS, as well as fundamental research about the nature of HIV as an infectious agent and AIDS as the disease caused by HIV.	16.000	18.000
Congressional Add: 459A - Peer-Reviewed Epilepsy Research ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for traumatic brain injury (TBI)-related epilepsy research. The Peer Reviewed Epilepsy Research Program supported studies to examine the interconnection between TBI and epilepsy in four scientific focus areas: (1) epidemiology; (2) markers and mechanisms of post traumatic epilepsy; (3) models of post-traumatic epilepsy; and (4) research into psychogenic (non-epileptic) seizures. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for traumatic brain injury (TBI)-related epilepsy research. The Peer Reviewed Epilepsy Research Program supported studies to examine the interconnection between TBI and epilepsy in four scientific focus areas: (1) epidemiology; (2) markers and mechanisms of post traumatic epilepsy; (3) models of post-traumatic epilepsy; and (4) research into psychogenic (non-epileptic) seizures.	12.000	12.000
Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative was directed toward 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. ***FY 2022 Plans:*** This Congressional Special Interest initiative was directed toward DHP core research initiatives in PE 0603115. Funds supported medical technology development efforts in the areas of military operational	221.215	212.980

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
medicine, combat casualty care, military infectious diseases, clinical and rehabilitative medicine, medical simulation and information sciences, and radiation health effects.		
Congressional Add: 495 - Peer-Reviewed Tick-Borne Disease Research ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for tick-borne diseases research. The 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. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for tick-borne diseases research. The 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.	7.000	7.000
Congressional Add: 496 -Trauma Clinical Research Program ***FY 2021 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. ***FY 2022 Plans:*** 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.	10.000	10.000
Congressional Add: 501 - Peer-Reviewed Hearing Restoration Research (Army)	10.000	10.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
FY 2021 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. ***FY 2022 Plans:*** 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.		
Congressional Add: 502 - CSI - Peer-Reviewed Kidney Cancer Research (Army) ***FY 2021 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. ***FY 2022 Plans:*** 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.	50.000	50.000
Congressional Add: 503 - CSI - Peer-Reviewed Lupus Research (Army) ***FY 2021 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. ***FY 2022 Plans:*** 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.	10.000	10.000
Congressional Add: 540A - Global HIV/AIDS Prevention (Navy) ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for research for Global HIV/AIDS Prevention. The program is responsible for assisting foreign military partners with the	8.000	10.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
development and implementation of culturally focused, military-specific HIV/AIDS prevention, care, and treatment programs in more than 55 countries around the globe. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for research for Global HIV/AIDS Prevention. The program is responsible for assisting foreign military partners with the development and implementation of culturally focused, military-specific HIV/AIDS prevention, care, and treatment programs in more than 55 countries around the globe.		
Congressional Add: 660A - Tuberous Sclerosis Complex (TSC) ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for Tuberous Sclerosis Complex (TSC) research. The Tuberous Sclerosis Complex Research Program (TSCRP) sought to support innovative research to improve the lives of individuals with TSC through understanding the pathogenesis and manifestations of TSC and developing improved diagnostic and treatment approaches. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for Tuberous Sclerosis Complex (TSC) research. The Tuberous Sclerosis Complex Research Program (TSCRP) sought to support innovative research to improve the lives of individuals with TSC through understanding the pathogenesis and manifestations of TSC and developing improved diagnostic and treatment approaches.	8.000	8.000
Congressional Add: 790A - Peer-Reviewed Duchenne Muscular Dystrophy ***FY 2021 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. ***FY 2022 Plans:*** 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.	10.000	10.000
Congressional Add: 512 - Peer-Reviewed Melanoma Research	30.000	40.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
FY 2021 Accomplishments: This Congressional Special Interest initiative provided funds for Peer-Reviewed Melanoma Research. The program is responsible for innovative research that will impact the prevention, diagnosis, staging, and treatment of melanoma in the near and intermediate future. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for Peer-Reviewed Melanoma Research. The program is responsible for innovative research that will impact the prevention, diagnosis, staging, and treatment of melanoma in the near and intermediate future.		
Congressional Add: 513 - Chronic Pain Management ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for Chronic Pain Management. The program is responsible to develop new approaches to alleviate Veterans' pain, which may result from spinal cord injury, burns, amputations, traumatic brain injury, cancer, or musculoskeletal conditions. The program explores ways to decrease medical and behavioral harms related to opioid use and misuse, improve access to effective complementary approaches to pain care, and help treatment options to address pain and improve function, among other areas. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for Chronic Pain Management. The program is responsible to develop new approaches to alleviate Veterans' pain, which may result from spinal cord injury, burns, amputations, traumatic brain injury, cancer, or musculoskeletal conditions. The program explores ways to decrease medical and behavioral harms related to opioid use and misuse, improve access to effective complementary approaches to pain care, and help treatment options to address pain and improve function, among other areas.	15.000	15.000
Congressional Add: 514 - Combat Readiness Medical Research ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for Combat Readiness Medical Research. This program focuses on research relating to forward-deployable solutions that can promptly address life threatening injuries and medical diagnostics, threats, and treatments, and medical threats and treatments for Service members in battlefield settings. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for Combat Readiness Medical Research. This program focuses on research relating to forward-deployable solutions that can promptly address life threatening injuries and medical diagnostics, threats, and treatments, and medical threats and treatments for Service members in battlefield settings.	10.000	10.000
Congressional Add: 515 - Peer-Reviewed Pancreatic Cancer Research	15.000	15.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022
FY 2021 Accomplishments: This Congressional Special Interest initiative provided funds for Peer-Reviewed Pancreatic Cancer Research. The program support research on the prevention, detection, diagnosis, and treatment of pancreatic cancer. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for Peer-Reviewed Pancreatic Cancer Research. The program support research on the prevention, detection, diagnosis, and treatment of pancreatic cancer.		
Congressional Add: 516 - Peer-Reviewed Rare Cancers Research ***FY 2021 Accomplishments:*** This Congressional Special Interest initiative provided funds for Peer-Reviewed Rare Cancers Research. The program support research on the prevention, detection, diagnosis, and treatment of rare cancer. ***FY 2022 Plans:*** This Congressional Special Interest initiative provided funds for Peer-Reviewed Rare Cancers Research. The program support research on the prevention, detection, diagnosis, and treatment of rare cancer.	17.500	17.500
Congressional Add: 517 - Peer-Reviewed Scleroderma Research ***FY 2021 Accomplishments:*** Congressional Add ***FY 2022 Plans:*** N/A	5.000	0.000
Congressional Add: 300A - Congressional Add - Brain injury and disease prevention research ***FY 2021 Accomplishments:*** FY21 Congressional Add ***FY 2022 Plans:*** FY22 Congressional Add	61.682	60.000
Congressional Add: 300A - Congressional Add - Clinical research ***FY 2022 Plans:*** FY22 Congressional Add	-	10.000
Congressional Adds Subtotals	1,763.897	1,772.980

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 238C / *Air & Space Austere Environment Patient Care and Transport (AF)*	

COST ($ in Millions)	Prior Years (+)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
238C: *Air & Space Austere Environment Patient Care and Transport (AF)*	14.921	11.250	12.675	12.866	0.000	12.866	13.122	13.386	13.653	13.927	Continuing	Continuing

(+) The sum of all Prior Years is $0.295 million less than the represented total due to several projects ending

A. Mission Description and Budget Item Justification

This project advances combat casualty care in the air through biomedical research into interventional strategies and technologies that mitigate the risks for additional insult due to aeromedical evacuation. It transitions promising Science and Technology (S&T) from PE 0602115DHA's Project Code 306D - Biomedical Impact and Readiness Optimization of Air & Space Operations, and civilian groups into knowledge and materiel products that promote the recovery and return to duty of injured or ill service members, from point of injury back to definitive care.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Air & Space Austere Environment Patient Care and Transport (AF)	11.250	12.675	12.866	0.000	12.866
Description: Advanced research and development to model, improve and optimize enroute care systems in multi-domain operations. Efforts include S&T to provide autonomous patient care, telemedicine and decision-assist algorithms, impact of transport on patient pathophysiology, and optimization of care provider performance and stabilization / resuscitation strategies to improve service member survival and return to duty. ***FY 2022 Plans:*** Continue efforts to develop military-relevant models of injury and clinical progression during enroute care, advancing technologies for autonomous patient care and decision-assist, equipment with reduced size, weight and power or cold-chain management requirements, as well as continue to optimize labor and resource requirements for future medical combat casualty care operations. ***FY 2023 Base Plans:*** Understanding the effects of multiple flights following impact and blast-induced traumatic brain injury on long-term outcomes, automated decision support, telemedicine, telementoring, telemonitoring (TM3) and advancing technologies for autonomous patient care and decision-assist. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:***					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 238C / *Air & Space Austere Environment Patient Care and Transport (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Increase is due to inflation.					
Accomplishments/Planned Programs Subtotals	11.250	12.675	12.866	0.000	12.866

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
• BA-1, PE 0807714HP: *Other Consolidated Health Support*	-	-	-	-	-	-	-	-	-		

Remarks

Accomplishments: Transitioned technology to provide closed-looped control of oxygen delivery, investigated multi-channel infusion pump (MCIP), clinical evaluation of En Route Care outcomes, advanced telemedicine, telementoring, and telemonitoring (TM3), investigated En Route Care competencies, effects of multiple flights following impact and blast-induced Traumatic Brain Injury, effects of hypobaria following head trauma combined with hemorrhagic shock, and resuscitation strategies to improve outcomes from trauma and hemorrhagic shock.

D. Acquisition Strategy

Air Force contracting, Interagency Agreements, and Inter-service Support Agreements with the U.S. Army, U.S. 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 Announcements (BAA) and Intramural calls for proposals, which are used to award initiatives in this project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and / or regulatory approvals (IRB, etc.).

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 284B / *Air & Space Physiology, Medicine and Human Performance (AF)*	

COST ($ in Millions)	Prior Years (+)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
284B: *Air & Space Physiology, Medicine and Human Performance (AF)*	11.156	10.418	11.122	11.471	0.000	11.471	11.700	11.933	12.172	12.415	Continuing	Continuing

(+) The sum of all Prior Years is $0.205 million less than the represented total due to several projects ending

A. Mission Description and Budget Item Justification

This project enables, sustains, and optimizes performance of Airmen through the elevation and alleviation of health effects associated with Air Force (AF) operational missions. This work addresses operational environments such as the mitigation of stress in AF personnel, to include aircrew, care providers, aircraft maintainers, intelligence, surveillance and cyber operators, as well as remote piloted aircraft operators.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Air & Space Physiology, Medicine and Human Performance (AF)	10.418	11.122	11.471	0.000	11.471
Description: Advanced technology development to enable, sustain, and optimize cognitive, behavior and physiologic performance in high-priority career fields for the United States Air Force (USAF) and in multi-domain operations. The sub-project areas include cognitive and physiologic performance under operational and environmental stressors, detection and improvement of physiological performance, and safety via sensors and targeted conditioning, which includes training techniques for optimal performance.					
FY 2022 Plans: FY 2022 plans continue efforts as outlined in FY 2021. Specific focus includes updating air breathing standards for On-Board Oxygen Generating System (OBOGS) Aircraft to reduce UPEs and updating alignment criteria for Distributed Common Ground System (DCGS), Cyber, Surveillance, Intelligence, and Remotely Piloted Aircraft service members.					
FY 2023 Base Plans: To provide evidence-based test battery for physical attributes associated with G-performance, Fighter Aircrew Conditioning Program (FACP) update recommendations, Updated cognitive models associated with performance in DCGS environments, Modernized vision screening methodologies, and characterize the additive effects of the pilot flight ensemble and associated changes in the human response.					
FY 2023 OCO Plans:					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 284B / *Air & Space Physiology, Medicine and Human Performance (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Increase is due to inflation					
Accomplishments/Planned Programs Subtotals	10.418	11.122	11.471	0.000	11.471

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Accomplishments: Automated Vision Tester (AVT) software integrated into automated prototype and advanced .remote vision system medical vision standards, characterized neurocognitive and cardiac effects of sleep deprivation on altitude and G-tolerance, and GLOC detection algorithm development.

D. Acquisition Strategy

Air Force contracting, Interagency Agreements, and Inter-service Support Agreements with the U.S. Army, U.S. 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 Announcements (BAA) and Intramural calls for proposals, which are used to award initiatives in this project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and / or regulatory approvals (IRB, etc.).

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	17.469	0.232	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 project develops validated solutions for the delivery of preventative care, intervention and treatment to Active Duty members and DoD beneficiaries. The primary focus areas include physiological and psychological health. Sub-topics include resilience, personalized medicine, patient safety, and care coordination.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Operational Medicine Research & Development (Budgeted) (AF)	0.232	0.000	0.000	0.000	0.000
Description: 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. ***FY 2022 Plans:*** N/A ***FY 2023 Base Plans:*** N/A ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Reduced funding due to realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0603115DHA, Project Codes 285A, 308B, 238C, 284B, and 307B to focus on future readiness mission and operational medical capabilities required to support the warfighter.					
Accomplishments/Planned Programs Subtotals	0.232	0.000	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

C. Other Program Funding Summary ($ in Millions)

Remarks

Accomplishments: Genetic risk factors for pulmonary disorders were investigated, development progressed on a self-repairing dental material, military separation and retirement practices were investigated by health care providers to minimize diabetes risk, and smart hydrogels were evaluated as a method for graft targeted immunotherapy in reconstructive transplantation.

D. Acquisition Strategy

Broad Area Announcements (BAA) and Intramural calls for proposals are used to award initiatives in this project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and / or regulatory approvals (IRB, etc.).

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 307B / *Air & Space Force Health Protection (AF)*	

COST ($ in Millions)	Prior Years (+)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
307B: *Air & Space Force Health Protection (AF)*	29.148	10.046	11.463	11.630	0.000	11.630	11.862	12.098	12.340	12.586	Continuing	Continuing

(+) The sum of all Prior Years is $0.362 million less than the represented total due to several projects ending

A. Mission Description and Budget Item Justification

This project delivers improved capabilities across the full spectrum of Air Force (AF) operations in the areas of directed energy and occupational and environmental health. Research involves the assessment and implementation of innovative technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, directed energy, and other radiological and physical hazards that present a health risk to our Airmen and threaten to degrade and disrupt operational readiness. The intent is to warn and protect AF operators, such as our high performance and high-altitude aircrews facing extreme environments.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Air & Space Force Health Protection (AF)	10.046	11.463	11.630	0.000	11.630
Description: Advanced research to develop and model exposures within the realms of Airman occupation, expeditionary medicine, medical countermeasures of directed energy, aircrew health, and CBRNE environments as it relates to health readiness. This project area seeks to deliver improved capabilities across the full spectrum of Air Force operations to enable force health protection.					
FY 2022 Plans: To analyze detected threats and stressors using human model development (an in silico / in vitro tool to understand the impact of environmental and chemical stresses on the human) enroute to utilizing mitigation strategies coordinated with the operational community.					
FY 2023 Base Plans: To field exposure sensor flow process screening through human health machine learning algorithms for: real-time performance predictions, integrate high throughput toxico kinetics framework, understand limits of detection in operational environment.					
FY 2023 OCO Plans: N/A					
FY 2022 to FY 2023 Increase/Decrease Statement:					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 307B / *Air & Space Force Health Protection (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Increase due to inflation					
Accomplishments/Planned Programs Subtotals	10.046	11.463	11.630	0.000	11.630

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Accomplishments: Developed individual exposure health risk profiles associated with chemical and noise exposures, conducted COVID-19 aircraft decontamination efforts to understand aircraft contamination and disinfection optimization, advanced exposure assessment tools for Total Exposure Health, and CBRN health assessment and risk tool (CHART) upgrade.

D. Acquisition Strategy

Air Force contracting, Interagency Agreements, and Inter-service Support Agreements with the U.S. Army, U.S. 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 Announcements (BAA) and Intramural calls for proposals, which are used to award initiatives in this project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and / or regulatory approvals (IRB, etc.).

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	21.391	2.623	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

(+) The sum of all Prior Years is $0.173 million less than the represented total due to several projects ending

A. Mission Description and Budget Item Justification

This project area identifies innovative techniques and technologies that can be employed by Air Force medics during prolonged field care operations. It includes technology to improve survivability and advance “zero-preventable deaths”. Sub-project areas include the development and validation of novel procedures, materials, techniques, and tools associated with expeditionary operations.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Expeditionary Medicine Research & Development (Budgeted) (AF) ***Description:*** This project provides advanced technology development to improve regenerative medicine and stabilization in prolonged field care operations. Efforts will include enhanced clinical guidelines and concept technology for treatment of non-compressible torso hemorrhage, development and application of portable ventilation monitoring, and development of new life and limb salvage technologies.	2.623	-	-	-	-
Accomplishments/Planned Programs Subtotals	2.623	-	-	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Accomplishments: Therapies to restore peripheral nerve regeneration were evaluated, development progressed on a portable ventilation monitoring capability, surgical methods and therapeutics were assessed to assist in prolonged field care / delayed evaluation applications, a teleophthalmology (tele-optometry) protocol was developed for military ophthalmologists, and medicine stability in high humidity and extreme temperatures was evaluated.

D. Acquisition Strategy

Broad Area Announcements (BAA) and Intramural calls for proposals are used to award initiatives in this project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and / or regulatory approvals (IRB, etc.).

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
309A: *Regenerative Medicine (USUHS)*	25.909	10.413	10.621	10.833	0.000	10.833	11.051	11.271	11.496	11.724	Continuing	Continuing

(+) The sum of all Prior Years is $0.342 million less than the represented total due to several projects ending

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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Center for Neuroscience and Regenerative Medicine (USUHS)	10.413	10.621	10.833	0.000	10.833
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 131 research projects.					
FY 2022 Plans: FY 2022 Plans: (1) Design and execute rigorous clinical trials of candidate therapeutics with potential for direct benefit to military service members with TBI. There are 7 randomized controlled trials ongoing or in late-stage development, and several more in the planning stages. All trials involve U.S. military service members with readiness-relevant health concerns related to TBI, such as post-traumatic headaches, sleep disorders, and mood dysregulation. This objective involves building and maintaining a network of site collaborators and staff at multiple military treatment facilities around the U.S. (2) Execute a major observational study on the effects of repeated subconcussive blast exposures sustained during military heavy weapons training. This ongoing study involves objective assessments of Navy SEALs, range safety officers, and unexposed controls at multiple time points to assess baseline, acute, subacute and chronic effects.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
(3) Test 2 novel handheld devices designed for prolonged field care use by military pre-hospital providers. These include a) an ultralight intracranial hemorrhage detector that uses advanced infrared technology to localize life-threatening subdural and epidural hematomas without the need for a Computed tomography (CT) scanner; b) a fully self-contained tight seal burr hold device that will allow emergency treatment of life-threatening subdural and epidural hematomas in an austere environment by prehospital providers. These devices will be tested in a sheep model of subdural hematoma in collaboration with the Walter Reed Army Institute for Research (WRAIR) and the Johns Hopkins Applied Physics Lab. (4) Train future military TBI research leaders through a post-doctoral fellowship program in collaboration with the University of Maryland, direct mentoring of military researchers around the country, a weekly seminar series, and multiple other educational events. (5) Perform discovery research that lays a foundation for future clinical trials, including a) use of a military relevant TBI mouse model involving combined repetitive blasts, plus impact, plus chronic stress to test candidate therapeutics, b) discovery of new magnetic resonance imaging (MRI) methods to detect blast-related brain injury, which at present can only be assessed post-mortem, c) development and validation of blood and sweat-based biomarkers for objective assessment of TBI. (6) Provide efficient, high quality support services for CNRM researchers and collaborators: a) the clinical trials unit, including protocol development, regulatory, and monitoring services; b) informatics, including secure clinical data capture, robust data storage, and rigorous statistical analysis; c) biofluid core, including robust storage, distribution of samples to collaborators, and analyses, including high sensitivity biomarker studies in sweat, saliva and blood; d) program management, including personnel, financial, logistics, safety, and compliance activities. (7) Continuously communicate with stakeholders to refine focus areas, funding priorities, and collaborative opportunities. (8) Focus on improving diversity, equity and inclusion through a series of workshops, readings, and team activities. (9) Disseminate findings of CNRM research to military, medical, scientific, and lay communities via in-person events, social media, electronic communications, and peer reviewed publications.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
(10) Expand CNRM funding via external sources to support additional clinical trials, blast exposure studies, prolonged field care activities, and discovery research with a goal of doubling our current total funding by 2030. ***FY 2023 Base Plans:*** FY 2022 plans continue efforts as outlined in FY 2021. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Price adjustment for inflation.					
Accomplishments/Planned Programs Subtotals	10.413	10.621	10.833	0.000	10.833

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
• BA-1, 0806721HP: *Uniformed Services University of the Health Sciences*	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

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373 / *GDF - Medical Technology Development*	

COST ($ in Millions)	Prior Years (+)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
373: *GDF - Medical Technology Development*	401.932	5.001	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

(+) The sum of all Prior Years is $5.000 million less than the represented total due to several projects ending

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 Joint Program Committees in the following areas: 1- Military Infectious Diseases research is developing protection and treatment capabilities for military relevant emerging infectious diseases and wound infections. 2- 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 readiness of Service members. 3- 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: GDF – Medical Technology Development	5.001	0.000	0.000	0.000	0.000
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 2022 Plans:*** N/A $0 ***FY 2023 Base Plans:*** N/A $0 ***FY 2023 OCO Plans:*** N/A $0 ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Congressional Add-Restoral					
Accomplishments/Planned Programs Subtotals	5.001	0.000	0.000	0.000	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373 / *GDF - Medical Technology Development*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373A / *GDF - MTD (Combat Casualty Care)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
373A: *GDF - MTD (Combat Casualty Care)*	0.000	11.168	15.736	24.519	0.000	24.519	26.943	27.950	28.871	29.810	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project supports Medical Technology Development (combat casualty care) efforts with the goal of optimizing Warfighter survival and recovery from combat-related injury in current and future operational scenarios for the acute and early management of combat-related trauma, including point of injury, en route, and facility-based care.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Joint Battlefield Healthcare (Formerly Combat Casualty Care)	11.168	15.736	24.519	0.000	24.519

Description: Joint Battlefield Healthcare (formerly Combat Casualty Care) medical technology development activities seek to drive medical innovation through development of knowledge and materiel solutions for the management of combat-related trauma.

FY 2022 Plans:
Joint Battlefield Healthcare (formerly Combat Casualty Care) medical technology development will focus on evaluating diagnostic tools and treatments designed for deployment during multi-domain operations, resource-limited conditions and prolonged care. Test effective critical care processes and technologies for severe casualties injured during large scale combat operations. These technologies include devices to treat tissue damage caused when blood supply returns to tissue after a period of oxygen deprivation, technologies for advanced hemorrhage control, novel blood products, technologies for autonomous vascular access, battlefield burn diagnostics and management, and advanced en route casualty treatment and management.

FY 2023 Base Plans:
Joint Battlefield Healthcare (formerly Combat Casualty Care) medical technology development will continue to focus on developing and transitioning emerging technologies to enable care in the areas of prolonged field care, pre-hospital tactical combat casualty care, battlefield traumatic brain injury/neurotrauma, burn injury, and en route care.

FY 2023 OCO Plans:
N/A

FY 2022 to FY 2023 Increase/Decrease Statement:

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - MTD (Combat Casualty Care)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Funds moved from Project Code 373C to further support Joint Battlefield Healthcare (formerly Combat Casualty Care) technology development efforts to optimize survival and recovery from combat-related injury in current and future operational scenarios.					
Accomplishments/Planned Programs Subtotals	11.168	15.736	24.519	0.000	24.519

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

N/A

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373B / *GDF - MTD (Military Operational Medicine)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
373B: *GDF - MTD (Military Operational Medicine)*	0.000	23.255	19.046	34.150	0.000	34.150	32.426	33.152	33.815	34.492	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project supports medical technology development efforts with the goal of maximizing the health, readiness, and performance of Service members and their families by the development of effective biomedical countermeasures against operational stressors, and prevention and treatment of physical and psychological injuries during training and operations.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Military Health and Recovery (Formerly Military Operational Medicine)	23.255	19.046	34.150	0.000	34.150
Description: Military Health and Recovery (Formerly Military Operational Medicine) medical technology and development efforts focus on the following areas: musculoskeletal injury prevention and treatment; blunt, blast, accelerative, and neurosensory injury prevention & readiness; psychological health and resilience; performance in extreme environments; and optimized cognition and fatigue mitigation.					
FY 2022 Plans: Efforts will focus on: injury prevention and recovery related to musculoskeletal injury; fatigue, cognitive health and performance; human operator health and performance in complex systems; operational systems toxicology for environmental health hazards; protection and performance sustainment in extreme environments; optimization of psychological health and resilience; and diagnosis & treatment of mental health disorders.					
FY 2023 Base Plans: Efforts will continue to focus on: injury prevention and recovery related to musculoskeletal injury; fatigue, cognitive health and performance; human operator health and performance in complex systems; operational systems toxicology for environmental health hazards; protection and performance sustainment in extreme environments; optimization of psychological health and resilience; and diagnosis & treatment of mental health disorders.					
FY 2023 OCO Plans: N/A					
FY 2022 to FY 2023 Increase/Decrease Statement:					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373B / *GDF - MTD (Military Operational Medicine)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Funds moved from Project Code 373D to support additional Military Health and Recovery (Formerly Military Operational Medicine) musculoskeletal injury prevention & treatment technology development efforts.					
Accomplishments/Planned Programs Subtotals	23.255	19.046	34.150	0.000	34.150

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373C / *GDF - MTD (Medical Simulation & Training/Health Informatics)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
373C: *GDF - MTD (Medical Simulation & Training/Health Informatics)*	0.000	12.613	13.044	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Conduct proof of technological feasibility studies and experiments and/or assessment of operability and producibility to address a military medical need identified through the Joint Capabilities Integration and Development System. Efforts are directed towards prototypes for field experiments and/or tests in a simulated environment, assessment/proof of feasibility or demonstration of utility/cost reduction that support medical simulation to increase military medical personnel's knowledge, skills and abilities to deliver combat casualty care support to manage patient injury and illness and to conduct patient movement from point of injury through role of care four.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Medical Simulation Technologies (Formerly Medical Simulation Technologies & Training/Health Informatics)	12.613	13.044	0.000	0.000	0.000
Description: Studies, investigations, and non-system specific technology effort focus on prototyping tissue models, technologies that simulate medical condition progress over time, technologies that simulate injury, technologies that replicate warfighter bio-physiology, and, technologies that simulate high-fidelity combat casualty care scenarios. Activities will continue to focus on tissue models that accurately simulate the feel, pliability, flexibility, and responsiveness of live tissue; technologies that simulate the degradation or worsening of a medical condition over time, as well as simulate the improvement of a medical condition over time; technologies that simulate injury, especially hemorrhage, fractures, and ocular damage; technologies that accurately reflect warfighter bodily characteristics and are rugged enough to simulate patient care and movement throughout the entire continuum of care; technologies that simulate combat scenarios to provide realistic environments; and, technologies that simulate patient movement through the continuum of care.					
FY 2022 Plans: N/A					
FY 2023 Base Plans: N/A					
FY 2023 OCO Plans:					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373C / *GDF - MTD (Medical Simulation & Training/Health Informatics)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Funds moved to Project Codes 373A and 373E to support Joint Battlefield Healthcare (formerly Combat Casualty Care) and Military Infectious Disease (wound infections) medical technology development efforts.					
Accomplishments/Planned Programs Subtotals	12.613	13.044	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373D / *GDF - MTD (Clinical and Rehabilitation Medicine)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
373D: *GDF - MTD (Clinical and Rehabilitation Medicine)*	0.000	13.040	14.980	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Clinical and rehabilitative medicine activities continue to develop knowledge and materiel products to reconstruct, rehabilitate, and provide care for injured Service member is the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and sensory systems.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Clinical and Rehabilitation Medicine	13.040	14.980	0.000	0.000	0.000
Description: Clinical and rehabilitation medicine efforts will continue to support clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment, and rehabilitation outcomes for Service-related injuries. Develop solutions (knowledge and materiel) for the diagnosis and alleviation of pain, restoration or regeneration of neuromusculoskeletal tissues, and sensory system (ocular) rehabilitation and treatment. ***FY 2022 Plans:*** N/A ***FY 2023 Base Plans:*** N/A ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Funds moved to Project Code 373B (Military Health and Recovery (Formerly Military Operational Medicine).					
Accomplishments/Planned Programs Subtotals	13.040	14.980	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373D / *GDF - MTD (Clinical and Rehabilitation Medicine)*

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373E / *GDF - MTD (Military Infectious Disease)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
373E: *GDF - MTD (Military Infectious Disease)*	0.000	6.409	6.630	12.886	0.000	12.886	13.817	13.747	13.659	13.570	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project supports medical technology development efforts toward the goal of preventing and treating infectious disease threats to eliminate their impacts on operational readiness.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Military Infectious Disease	6.409	6.630	12.886	0.000	12.886
Description: Military infectious disease activities to support efforts (including clinical) to develop innovative therapeutics and delivery technologies for combat wound infections. These efforts include accelerating promising prevention and treatment solutions to emerging infectious diseases (e.g., Dengue, chikungunya, Coronaviruses).					
FY 2022 Plans: Test lead drug candidates in healthy volunteers to determine drug pharmacology, safety, and effectiveness against emerging infectious diseases (EID). Transition the lead EID drug with improved safety, effectiveness and less frequent dosing to advanced development. Perform small studies in healthy volunteers to test safety, effectiveness and immunogenicity of immunoprophylactics (to prevent disease by immunity) against EID with down-selection and transition of the immunoprophylactics to advanced development. Manufacture EID vaccine candidate for clinical testing. Perform clinical testing of EID vaccine candidates for safety and efficacy in humans. Manufacture dengue vaccine candidate for clinical testing. Perform clinical testing of dengue vaccine candidates for safety and efficacy in humans. Support wound infections prevention and treatment medical technology and development efforts.					
FY 2023 Base Plans: Will continue to test lead drug candidates in healthy volunteers to determine drug pharmacology, safety, and effectiveness against emerging infectious diseases (EID). Will continue to support wound infections prevention and treatments research.					
FY 2023 OCO Plans:					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373E / *GDF - MTD (Military Infectious Disease)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Funds moved from 373C to support Military Infectious Diseases wound infections technology development efforts.					
Accomplishments/Planned Programs Subtotals	6.409	6.630	12.886	0.000	12.886

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373F / *GDF - MTD (Radiological Health Effects)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
373F: *GDF - MTD (Radiological Health Effects)*	0.000	0.501	0.518	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 supports medical technology development efforts with the goal of pursuing the development of Food and Drug Administration (FDA) approved drugs, biologicals, and diagnostics (e.g., biodosimetry) to increase survival and decrease incapacity after acute radiation exposures.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Radiological Health Effects	0.501	0.518	0.000	0.000	0.000
Description: Develop in vivo models, assays, and other enabling technologies to support transition of candidate MCM(s) and to reduce risk during advanced development. This efforts will include the identification and characterization of biomarkers to establish novel druggable targets, understanding differences in species sensitivity to radiation, evaluating direct and indirect mechanisms of actions of high and low linear energy transfer (LET) radiation sources (e.g., neutrons, gamma), and, determining radiosensitivity and radioresistance of various systems/organs. ***FY 2022 Plans:*** Support research toward the development of Food and Drug Administration (FDA) approved drugs, biologicals, and diagnostics (e.g., biodosimetry) for acute radiation exposures to increase survival and decrease incapacity. ***FY 2023 Base Plans:*** N/A ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Program combined with 373A Joint Battlefield Healthcare (formerly Combat Casualty Care)					
Accomplishments/Planned Programs Subtotals	0.501	0.518	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373F / *GDF - MTD (Radiological Health Effects)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373G / *GDF - MTD (Military Medical Photonics)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
373G: *GDF - MTD (Military Medical Photonics)*	0.000	10.000	10.200	10.404	0.000	10.404	10.612	10.824	11.040	11.261	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project supports Military Medical Photonics applied research with the goal of optimizing Warfighter survival and recovery from combat-related injury in current and future operational scenarios by driving medical innovation through development of knowledge and materiel solutions for the acute and early management of combat-related trauma, including point of injury, en route, and facility-based care.

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Military Medical Photonics	10.000	10.200	10.404	0.000	10.404
Description: The Military Medical Photonics Program is an interdisciplinary program of physical and biological scientists, engineers, and physicians addressing diagnostic and therapeutic needs to support combat casualty care. Activities will continue to focus on diagnostic, imaging, and therapeutic studies. Specific efforts include: Photochemical tissue bonding for wound repair, passivation, and vein stiffening for abnormal connections between an artery and a vein; Optical applications for treatment and prevention of wound contamination and scarring, and to support wound healing and cartilage regeneration; Photonics-based diagnostics, including early detection of airway inhalation injury and implantable biomarker sensors; Investigations of photonics technologies to support the prolonged shelf life of human platelets; and Photobiomodulation to affect cognitive function.					
FY 2022 Plans: Conduct research toward the development of diagnostic, assessment and therapeutic solutions to optimize medical care of the Warfighter in current and future battlefield. Materiel and knowledge solutions will focus on innovative capabilities for use in the far forward environment that will cognitively and physically off load the medics in Large Scale Combat operations (LSCO). Focus areas will be cutting edge diagnostics that are of low cube and weight and can be used by minimally trained Warfighters at the point of injury, miniature and rugged imaging capabilities, and novel therapeutics for wound repair, vascular rupture diagnosis and repair. Photonics-based diagnostics will be integrated across the continuum of care, including early					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373G / *GDF - MTD (Military Medical Photonics)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
detection of airway inhalation injury and implantable biomarker sensors and Photobiomodulation to affect cognitive function. ***FY 2023 Base Plans:*** Will continue research toward the development of diagnostic, assessment and therapeutic solutions to optimize medical care of the Warfighter in current and future battlefield. Materiel and knowledge solutions will focus on innovative capabilities for use in the far forward environment that will cognitively and physically off load the medics in Large Scale Combat operations (LSCO). Focus areas will be cutting edge diagnostics that are of low cube and weight and can be used by minimally trained Warfighters at the point of injury, miniature and rugged imaging capabilities, and novel therapeutics for wound repair, vascular rupture diagnosis and repair. Photonics-based diagnostics will be integrated across the continuum of care, including early detection of airway inhalation injury and implantable biomarker sensors and Photobiomodulation to affect cognitive function. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Increase due to inflation					
Accomplishments/Planned Programs Subtotals	10.000	10.200	10.404	0.000	10.404

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 373H / *GDF - MTD (Medical Advanced Technology)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
373H: *GDF - MTD (Medical Advanced Technology)*	0.000	0.000	0.000	68.016	0.000	68.016	68.576	64.720	63.969	63.969	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding and mission realignment of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737) in support of Medical Systems, Advanced Technology & Development.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: GDF - MTD (Medical Advanced Technology) ***Description:*** Programmatic transfer in accordance with the 711/737 US Army Medical Research and Development Command transfer to Defense Health Agency in support of Medical Systems, Advanced Technology & Development from Army PEs 0603002A & 0603115A. ***FY 2022 Plans:*** N/A ***FY 2023 Base Plans:*** Efforts will focus on Advanced Technology Development of Medical Technology. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Funding increase for this Project was due to transfer/realignment from Army.	0.000	0.000	68.016	0.000	68.016
Accomplishments/Planned Programs Subtotals	0.000	0.000	68.016	0.000	68.016

	FY 2021	FY 2022
Congressional Add: N/A	0.000	0.000
FY 2021 Accomplishments: N/A		
FY 2022 Plans: N/A		
Congressional Adds Subtotals	0.000	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 373H / *GDF - MTD (Medical Advanced Technology)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 (USUHS))*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
378B: *CoE-Breast Cancer Center of Excellence (USUHS))*	29.843	10.685	10.898	11.116	0.000	11.116	11.339	11.566	11.797	12.033	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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Breast Cancer Center of Excellence	10.685	10.898	11.116	0.000	11.116
Description: The Readiness and Lethality of the Total Force is based in large part on personnel health. Nearly 20% of the active duty force is now female, and breast cancer is the number one cancer in active duty women, far surpassing all other causes of cancer in this population. The Breast Cancer CoE utilizes a multidisciplinary approach for researching breast diseases and breast cancer focused on the military at-risk active duty population in order to enhance Readiness of The Total Force. This multidisciplinary model integrates prevention, screening, early diagnosis, treatment and continuing care, but the project is further unique in the 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 and pathologically well-characterized tissue repository with advances in biomedical informatics leading to hypothesis-generating discoveries that are then tested in hypothesis-driven experiments. In addition to the primary achievement of research objectives, the program educates Federal employees as a benefit to the public they serve through Federal service, through support to civil authorities, and in non-Federal professional and academic collaborations. FY21 Accomplishments: - Accrued 307 breast patients to Breast CoE core protocols - Accrued 128 breast patients to the ORIEN research protocol - Acquired 3,428 new biospecimens at our Breast COE sites to the core tissue protocol - Utilized our biospecimens and data base in support of 28 publications from October 2020 to Present					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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 (USUHS))*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
- Performed critical research on young women with breast cancer, and the demographic of African-American women with breast cancer, key cohorts affecting cancer as a readiness issue for the DoD - Developed additional research work with NCI regarding young women with breast cancer in relation to the active duty component PATENT: Recurrence Gene Signature Across Multiple Cancer Types. (International Application #: PCT/US19/49688; entered National Phase on March 3, 2021) Provisional Patent Application “Protein markers for the prognosis of breast cancer progression” Murtha Cancer Center/Research Program Provisional Patent Application “Protein markers for estrogen receptor (ER)-positive-like and estrogen receptor (ER)-negative-like breast cancer” Murtha Cancer Center/Research Program Provisional Patent Application “Protein markers for estrogen receptor (ER)-positive luminal a (LA)-like and luminal b1 (LB1)-like breast cancer” Murtha Cancer Center/Research Program ***FY 2022 Plans:*** FY 2022 plans continue efforts as outlined in FY 2021. The Program will complete the following: Objective 1: Identify and consent a minimum of 150 patients (to include patients at high risk for development of breast cancer) annually to the MCCRP APOLLO germline sequencing research study, with special focus on active duty females as a Force Protection / Readiness sustainment issue to the DoD. Objective 2: Accrue over 500 patients annually to the “core” USU MCCRP/BC-COE protocols by consenting patients at the main clinical sites, with the main site being the Murtha Cancer Center’s Breast Center at WRNMMC, the military’s largest and only NAPBC (National Accreditation Program for Breast Centers) approved breast center in the entire DoD MHS. Objective 3: Expand our breast tissue acquisition to include more military veterans, by acquiring tissues and enrolling veterans in our protocols who are receiving care at VA hospitals in Palo Alto (California), Durham					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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 (USUHS))*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
(North Carolina), Puget Sound (Washington), and VA Dallas. Acquire through consented protocol acquisitions, over 5,000 specimens annually (neoplastic 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 with a new focus on veterans and being able to then look at any relationship between deployment history, environmental exposures, and their service record. Objective 4: Bank these biospecimens in the USU MCCRP's BC-COE Biorepository as the substrate for all molecular analyses carried out in USU MCCRP's BC-COE labs, as outlined in the USU MCCRP's BC-COE Core Protocols. Utilize this repository as the basis for intramural and extramural collaborations for secondary usage research. Objective 5: Because of the ongoing expansion into VA sites and as an extension of the continued modernization of our world-class biobank, develop additional new quality assurance programs and standard operating procedures for the Tissue Bank regarding these new elements and sites from the VA and others including conducting biospecimen science research. Objective 6: Conduct integrative profiling research for protein-expression based, clinically relevant breast cancer stratification. Objective 7: Breast cancer studies focused on two special patient groups bearing poor outcomes, who are enriched in the military active-duty military population: young women, and Black women. Objective 8: Focusing on samples from female veterans and female active duty service members with breast cancer, perform new heterogeneity studies, including cellular heterogeneity of tumor development environment and lineage heterogeneity within one physical cancer tumor. Objective 9: Studies on mechanistic understanding of breast cancer development from other perspectives, including genetic dispositions, exposure to environmental risks, access to healthcare, and impact of certain lifestyle factors as well as comorbidities. Objective 10: Breast cancer HER2 Targeted Therapy Optimization Objective 11: With the new addition of VA hospital sites for breast tissue collections and clinical data collation under research protocols, continued development and rollout of an informatics infrastructure system to support these new needs of BC-COE research. Objective 12: Analysis of the publicly available TCGA, CPTAC, and other large scale cancer study datasets. ***FY 2023 Base Plans:*** Continuation of objectives from FY22. ***FY 2023 OCO Plans:***					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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 (USUHS))*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Pricing adjustment for inflation.					
Accomplishments/Planned Programs Subtotals	10.685	10.898	11.116	0.000	11.116

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 (USUHS)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
379B: *CoE-Gynecological Cancer Center of Excellence (USUHS)*	26.088	9.341	9.528	9.719	0.000	9.719	9.913	10.111	10.313	10.519	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.

A. Mission Description and Budget Item Justification

The Gynecologic Cancer Center of Excellence (GYN-COE) is an integrated translational research program aimed at development of companion biomarkers and assays, clinical decision support tools, risk assessment algorithms, quality improvement initiatives, treatments, and interventions for patients with gynecologic tumors and cancers, among a growing proportion of active duty women in the Armed Services, veteran and retired populations. Molecular profiling of pre-cancerous and malignant lesions has also enabled development of diagnostic and chemo-preventive interventions across the most common pathologic uterine conditions, rare variants, and the aggressive and deadly metastatic and recurrent malignancies that affect women and corresponding readiness. The GYN-COE has been the leading research program in the U.S. to identify clinical features, biologic etiologies, and social determinants underlying racial and ethnic disparities in gynecologic cancers using population based as well as translational research methods. The GYN-COE program features both the largest tissue laser capture microscopy facility as well as the most robust mass spectrometry-based proteomics facility in the DOD, enabling the program to assess the generalized relevance of GYN-COE discoveries in other cancers that impact service members and readiness. The comprehensive research program supports the training of subspecialty gynecologic oncology surgeons, a fellowship program that has trained advanced pelvic surgeons to support wartime efforts for the past 50 years. The program also educates and trains medical students, interns and residents in women's health, telemedicine, wellness, wound-healing, hemorrhage, infections, pain management, resistance, resilience, palliative care and evidence-based medicine. The program has partnered with the National Cancer Institute in its educational and investigative activities over the past 20 years becoming a pillar program for the Murtha Comprehensive Cancer Center and the Uniformed Services University. The GYN-COE has also strengthened cancer capabilities, advanced the federal precision oncology initiatives, contributed to the COVID-response, enabled delivery of equitable care to female service members, veterans and beneficiaries, and ensured readiness of the female fighting force by addressing their gender-specific medical conditions.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Gynecological Cancer Center of Excellence	9.341	9.528	9.719	0.000	9.719

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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 (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
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. The GYN-COE leverages innovative research to enhance gynecologic cancer care from prevention to survivorship for service members, beneficiaries, and the civilian population. • To use extraordinary analytical capabilities in sample preparations combined with micro-scaled proteogenomic analysis for development of companion diagnostics, theragnostics, prognostics and prediction models for provision of precision medicine to gyn cancer patients as well as agnostically to all patients through pan cancer discovery • The throughput of our analytical facility will open up opportunities to expand our capabilities for proteogenomic tissue profiling of biopsy sized specimens to support ancillary studies of drug response and resistance in clinical trial patients aimed at repurposing of FDA-approved drugs for pan cancer treatment in partnership with public, private, and industry organizations. • Use of our technologies to support proteogenomic characterization of the world's most rare and yet most clinically devastating diseases in partnership with the Joint Pathology Center. • Deployment of our analytical expertise to support research involving COVID related threats, combat related disorders, and behavioral health disorders, such as PTSD and others that are prevalent in retired veterans. • To expand our racial disparities research using the PAIRED consortium to support investigation of any cancer type or other disease for which there are worse outcomes in minority populations. • To provide undergraduate and graduate medical training in advanced pelvic surgery and complex gynecologic conditions within the context of a specialized fellowship in gynecologic oncology that produces physician scientists fluent in the latest advances of precision medicine for gynecologic cancer patients • Continue to serve as the comprehensive cancer center for gynecologic oncology clinical trial patients of the National Institutes of Health and veterans from regional VA facilities • The Clinical Proteomics Platform in the GYN-COE processed and analyzed 2224 unique cancer specimens in 2019 with a variance of less than 10% ***FY 2022 Plans:*** Will continue efforts from FY 2021. In addition, will continue to build on studies examining molecular determinants of recurrent versus non-recurrent disease and how distribution of disease and post-surgical tumor residual influences outcome. Deep proteogenomic analyses will extend current state of the art technologies to reveal clinically actionable data that improves outcomes. Investigations of cancer health disparities and					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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 (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
retrospective clinical and translational research will include collaborative development of companion assays, clinical support tools and predictive analytics for therapeutic efficacy, prognosis, and survivorship care planning. Racial disparities investigations will extend to utilization of resources from TDAN, APOLLO-5/-6/-7, MCCRP and the NCI National Clinical Trials Network. Building collaborations with military health agencies to increase active duty and veteran focused GYN-research. ***FY 2023 Base Plans:*** Will continue efforts from FY 2021 and FY 2022. In addition, we will advance optimization and deployment of companion assays, clinical support tools and predictive analytics to improve racial and cancer health equity, military readiness, capabilities, efficiency, and outcomes. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Pricing Adjustment.					
Accomplishments/Planned Programs Subtotals	9.341	9.528	9.719	0.000	9.719

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
381: *CoE - Integrative Cardiac Health Care (USUHS)*	5.929	1.680	1.744	1.809	0.000	1.809	1.875	1.943	1.982	2.022	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. To address the gaps identified in the Cardiovascular Care Initial Capabilities Document (ICD) (CRM-2017.03.23)
2. Enhance the cardiovascular health and well-being of the Warfighter and the DoD community through innovative clinical research using precision techniques.
3. 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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Integrative Cardiac Health/Military Cardiovascular Outcomes Research	1.680	1.744	1.809	0.000	1.809
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. FY2021 Accomplishments (Selected): The MiCOR portfolio currently includes 19 total studies with two broad themes: 1. Prevention of cardiac events in ADSM (16 projects) 2. Evaluating cardiac impact of COVID-19 infection/vaccination (3 Projects) Major landmarks: - 5400 USNA midshipmen screened using novel electrocardiographic device in support of BUMED Sudden Cardiac Death Risk Assessment Project Authorization Letter. Serious cardiac abnormalities were identified in 0.46%. Cited in HASC preamble to NDAA for extension to other academies. Briefing Accessions Medical Standards Working Group scheduled for December 2021 to add enhanced cardiac screening to MEPS and DODMERB recruit screening, affecting 150,000 recruits annually. - Long Term Outcomes following Combat Injury- Retrospectively compared CV outcomes in 17,570 warfighters and demonstrated that combat injury is associated with significant increases in cardiac arrhythmias, hypertension, diabetes mellitus, and coronary artery disease. Additional grant funding from CDMRP for a prospective study sought; decision anticipated January 2022. -Peer-reviewed Papers Published: 56					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 381 / *CoE - Integrative Cardiac Health Care (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
-Books: 1 -Book Chapters: 7 -Invited Presentations: 5 -Scientific Conference Workshops/Panels: 4 -Scientific Conference Paper/Poster Presentations: 20 -Four studies completed enrolment in FY21 and are in final analysis. - Six studies in active enrollment. -Long Haul COVID randomized clinical trial of ivabradine in institutional review. -1,000,000 USAF EKGs transferred to DHA and currently under analysis for machine learning. -Sleep Disordered Breathing- Analysis of opioids and their impact on sleep disordered breathing has been completed and published. Analysis of the QT interval variability as the mortality predictor is 50% completed since January 2021. Expected completion Q4 FY2022. ***FY 2022 Plans:*** Continue enrollment and conduct of study schedules for the six studies in the active phase. -Finalize analysis on the four studies in the post completion stage. Disseminate results accordingly to high impact journals. -Complete regulatory tasks (IRB, agreements, protocol development, etc.) for remaining studies in order for those studies to enter the active research phase. - Convene national committee of experts to formulate “Guidelines for the Cardiovascular Care of the Tactical Athlete” in collaboration with DHA, American Heart Association, and the American College of Cardiology. Tactical athletes include active duty military, astronauts, police officers, and firefighters. -Perform machine learning on 1,000,000 legacy electrocardiograms linked with MDR to identify novel biomarkers of cardiac risk. -Complete analysis of 5000 sleep polysomnograms for evaluation of electrocardiographic biomarker as predictor of death. - Post Covid vaccine myocarditis registry in IRB review. - 1,000,000 USAF EKGs transferred to DHA and currently under analysis for machine learning - Registry of cardiovascular electrophysiology procedures - Peer-reviewed Papers Published: 56 - Books: 1					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 381 / *CoE - Integrative Cardiac Health Care (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
- Book Chapters: 7 - Invited Presentations: 5 - Scientific Conference Workshops/Panels: 4 - Scientific Conference Paper/Poster Presentations: 20 ***FY 2023 Base Plans:*** FY23 plans continue efforts outlined in FY21 and FY22. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Pricing adjustment for inflation.					
Accomplishments/Planned Programs Subtotals	1.680	1.744	1.809	0.000	1.809

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
382B: *CoE-Pain Center of Excellence (USUHS)*	9.508	1.945	2.014	2.084	0.000	2.084	2.156	2.230	2.277	2.327	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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Pain Center of Excellence (USUHS)	1.945	2.014	2.084	0.000	2.084
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. The center also supports knowledge translation activities that are aimed at integrating research findings into military medicine clinical practice and policy. In addition to the primary achievement of research objectives, the program educates Federal employees as a benefit to the public they serve through Federal service, through support to civil authorities, and in non-Federal professional and academic collaborations.					
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. The center also supports knowledge translation activities that are aimed at integrating research findings into military medicine clinical practice and policy. In addition to the primary achievement of research objectives, the program educates Federal employees as a benefit to the public they serve through Federal service, through support to civil authorities, and in non-Federal professional and academic collaborations.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 382B / *CoE-Pain Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
FY21 Accomplishments 1. Provided pain management advisory support to Congressionally Directed Medical Research Programs (CDPRP) and Clinical & Rehabilitative Medicine (CRMRP). In accordance with the Memorandum of Agreement with Defense Health Agency, provided advisory to support to DHA Deputy Assistant Director Medical Affairs and DHA Pain Management Clinical Support Service. 2. Collaborated with DHA stakeholders and Military Health System providers to implement key metrics of pain management and their associated clinical decision support tools (e.g., Opioid Prescriber Monthly Trend Report, Look Up Tool, Look Up Tool Dashboard, Opioid Registry) to support enterprise-wide process improvement. 3. Successfully implemented the Established and integrated Opioid Education and Naloxone Dispensing (OEND) program in DHA as part of the Quadruple Aim Performance Process (QPP) Plan. This activity included implementation of the Train-the-Trainer program across several Markets and Military Treatment Facilities. As such, naloxone prescribing rates have significantly increased across the DoD. 4. Led revisions and updates to the DoD Opioid Prescriber Safety Training (OPST) mandated by the 2015 Presidential Memorandum; Addressing Prescription Drug Abuse and Heroin Use and required for all DoD opioid prescribers. DVCIPM was the primary content developer for the initial FY 2017 OPST and was subsequently tasked with leading the content updates and revisions for 2021. As of June 2021, over 48,000 DoD prescribers have completed this training; over 5000 prescribers to date in 2021 alone. 5. As the designated CoE for DoD pain management, served as lead for revisions to DHA-Procedural Instruction 6025.04 Pain Management and Opioid Safety, translating emerging medical evidence and standards of practice into DoD pain management and opioid safety policy. 6. Engaged in many service activities to support research training and development for USU medical students, DoD residents, and DHA providers. These activities included mentoring several USU Capstone students, resulting in many posters and publications; implementing a residency research program at Walter Reed National Military Medical Center (WRNMMC); advising many WRNMMC Anesthesiology residents on their research projects; and providing support for research development for several military anesthesiologists.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 382B / *CoE-Pain Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
7. Obtained another large CDMRP grant with co-investigators from Johns Hopkins Applied Physics Laboratory and School of Nursing, Georgetown University, and multiple Military Treatment Facilities. The objective of the study is to examine disparities across the Military Health System in pain management, using an Intersectionalist Framework and Health Equity Measurement Framework. 8. Obtained a grant subaward as Co-Investigator, with Cognitive Medical Systems as the prime, from USAMRDC to develop standards aligned remote control for commercially available ventilator and IV pump across the NETCCN architecture, and to inform future work regarding regulatory and/or safety requirements 9. The Pain Registry Biobank, approved in FY 19, is a clinical data registry and tissue biobank for the advancement of pain-related research. This Biobank contains PASTOR survey data, the Defense and Veterans Pain Rating Scale (DVPRS), electronic health record data, and biospecimens, (blood and saliva) on targeted individuals eligible for care within the Military Health System. Biobank Sites at Walter Reed National Military Medical Center and Naval Medical Center San Diego are enrolling. Currently, there are 200 participants, and approx. 4000 frozen samples. Permission was recently obtained to collect consents virtually, and a process to document and verify COVID-19 exposure is being explored. Applications for use of the PR Biobank data and samples are being accepted, and will be reviewed by the PR Biobank Oversight Committee. Face to face enrollment was placed on hold in March 2020, but was resumed in early 2021. 10. Published 20 articles across a range of high-impact journals related to rehabilitation, pain medicine, anesthesiology, and health services research. 11. DVCIPM Director serving as the DoD representative to the National Institute of Health's (NIH) Interagency Pain Research Coordinating Committee (IPRCC) and the DoD Co-Chair for the HEC Pain Management Work Group. 12. Improve transitions of care from DoD to VA for Service members with complex pain conditions by continuing to integrate common or complementary DoD/VA standards for pain-related data collection and reporting, opioid safety initiatives and practices, patient and provider education; leading DoD execution of DoD/VA Joint Executive Committee (JEC) action plans for opioid safety.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 382B / *CoE-Pain Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
13. Provided pain management functional support to DHA for the transition of the Pain Assessment Screening Tool and Outcomes Report (PASTOR) to the DHA Survey Portal. PASTOR is currently in use by over 240 DoD providers at 20 MTF pain management specialty clinics (as of 1Aug21). 14. Completed the Joint Pain Education Program study funded by DHA. ***FY 2022 Plans:*** FY 2022 plans continue efforts as outlined in FY 2021. FY 2022 plans continue efforts as outlined in FY 2021. And include the following activities: 1. Conduct implementation science research, provide subject matter expert support for a diverse portfolio of DoD/DHA pain management/opioid safety activities and initiatives, and facilitate the development of evidence-based policies. DVCIPM will establish an evidence-based, synthesized evaluation framework for patient/public health materials - the Health Information to Action Pathway (HITAP) Framework, (2) examine the patient-centeredness of patient/public health materials targeting pain management and opioid safety, and (3) provide suggestions for improvements. 2. Support innovative research by continuing recruitment into the robust Pain Registry Biobank at both of its sites and conducting research that leverages PASTOR/PROMIS outcomes. 3. To conduct rigorous research that supports healthcare optimization in pain management and analgesia. This includes collaborative studies with the Johns Hopkins Applied Physics Laboratory (APL) to conduct a pilot study and the Defense Health Management System (DHMS) on multiple studies. There are a range of different big-data studies that DVCIPM is currently engaged in including: examination of analgesia pathways across many different surgical procedures; evaluation of healthcare variability in naloxone, opioid, and non-opioid pain medication prescribing; identification of factors associated with dispense and effects of tramadol versus opioids; and other health services research. 4. Conduct several studies aimed at evaluating anesthesiology and pain management training, workforce readiness, and career sustainment within medical school, residency, and practice settings 5. Provide functional support to integrate PASTOR at all remaining MTF pain management specialty clinics. 6. To conduct a study examining whether early treatment with NMDA-antagonist ketamine will decrease the likelihood of the development of chronic pain and PTSD using a mouse model. ***FY 2023 Base Plans:***					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 382B / *CoE-Pain Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
FY 2023 plans continue efforts as outlined in FY 2022 ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Pricing adjustment for inflation.					
Accomplishments/Planned Programs Subtotals	1.945	2.014	2.084	0.000	2.084

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	23.812	8.526	8.696	8.870	0.000	8.870	9.047	9.228	9.413	9.600	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: CoE-Prostate Cancer Center of Excellence (USUHS)	8.526	8.696	8.870	0.000	8.870
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 28,500 DoD health care beneficiaries under suspicion for prostate cancer, with longitudinal follow up to 24 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-					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
the-art research infrastructure and framework is providing education and training for over 100 next generation physicians, scientists, medical and graduate students within DoD medical institutions. ***FY 2022 Plans:*** FY 2022 plans continue efforts as outlined in FY 2021. Accomplishments (FY21): • The CPDR-Clinical Research Program now at WRNMMC, combines a multidisciplinary approach of prostate cancer screening, data collection, clinical diagnosis, and treatment, education and counseling, and prostate disease clinical trial research in an efficient, personal and patient-oriented manner. • The program continues to advance collaborations with NCI-Medical Oncologist to enhance treatment of advanced prostate cancer patients at WRNMMC. • The CPDR has enrolled patients in clinical trials for more than two decades. Currently, there are 8 ongoing clinical trials ranging from disease prevention to quality-of-life. • The CPDR provides for patient serum, urine, tissue bank and patient data registry by establishing and accelerating patient enrollment in the multicenter national database and biospecimen banking protocols. • The CPDR bio-specimens banks currently house more than 240,000 units of various types of specimens which are driving engines for ground breaking research focusing on new diagnostic and prognostic bio-markers and therapeutic targets through in-house and collaborative efforts. • The urine exosome prostate screening assay that earlier licensed the CPDR prostate cancer biomarkers is now reimbursed by Medicare, covered by CareFirst, BlueCross and BlueShield has reached FDA fast track (material product) • The CPDR validated Genomic Health Inc., biopsy tissue prognostic assay was incorporated into the NCCN recommendations (material product) • US Patent Applications filed on CPDR discoveries of prostate cancer genomic alterations of African American men (knowledge product) • New serum-based biomarker panels were developed using proteome, lipidome and metabolome analytes by using artificial intelligence in collaboration with BERG Health and US Patent Applications were filed (knowledge product) • New and more effective therapeutic derivatives of the compound ERGi-USU has been developed, a US Patent has been issued (material product)					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
• CPDR had major contribution for the development of a new genetic risk prediction score and to the recommendations for new genetic testing panels, published in high impact journals including, Nature Genetics vol. 53:65-75, 2021 and J Clin Oncol vol. 38:2798-2811, 2020 (knowledge products) Knowledge Products (FY21 - 12 Publications); Podium Presentations (FY21 - 3 Presentations); Poster Presentations (FY21 – 13 Presentations) Training (FY21 – 9 Students, USU SOM, WRNMMC Urology resident, US Naval Academy) Materiel Products (FY21) Issued Patents and Patent Application (7) Issued U.S. Patent Genomic Rearrangements Associated with Prostate Cancer and Methods of Using the Same PCT/US2020/10,711,311B2, Issued: July 14, 2020 Issued Foreign Patent Prostate Cancer-Specific Alterations in ERG8 Gene Expression and Detection and Treatment Methods Based on Those Alterations: Canadian Patent 2,719,172, August 25, 2020 U.S. PCT (Non-Provisional) Patent Applications Markers for the Diagnosis of Prostate Cancer: USPA 16/91,775 June 26, 2020 Revised USU Form 3210 – March 2015 Page 4 of 11 Protein Panels for the Early Diagnosis/Prognosis and Treatment of Aggressive Prostate Cancer: USPA: 62/888,890 August 19, 2020 DNA Damage Repair Genes in Prostate Cancer, International PCT Application PCT/US21/21136 filed on March 5, 2021 (claiming priority to US Provisional 62/985,996 filed on March 6, 2020) ***FY 2023 Base Plans:*** Plans continue efforts as outlined in FY21 and FY22. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Pricing adjustment for inflation.					
Accomplishments/Planned Programs Subtotals	8.526	8.696	8.870	0.000	8.870

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
431A: *Underbody Blast Testing (Army)*	68.611	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

To better protect mounted warriors from the effects of underbody blast (UBB) caused by landmines or Improvised Explosive Devices (IEDs), 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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Underbody Blast Testing ***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.	0.000	-	-	-	-
Accomplishments/Planned Programs Subtotals	0.000	-	-	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Produce BRC and human injury probability curves for human skeletal response and tolerance in the military UBB environment and transition them to the Program Execution Office for Simulation, Training and Instrumentation for use in the development of the WIAMan UBB test manikin and for general use in the research,

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 431A / *Underbody Blast Testing (Army)*

development, test and evaluation community. Develop injury assessment reference curves for use with WIAMan manikin to support vehicle and protection technology acquisition decisions.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
448A: *Military HIV Research Program (Army)*	46.516	0.000	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 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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Military HIV Research Program ***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.	0.000	-	-	-	-
Accomplishments/Planned Programs Subtotals	0.000	-	-	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

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.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
478: *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*	48.076	18.640	18.724	19.058	0.000	19.058	19.480	19.870	20.267	20.672	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 ADSMs who are stricken with a new cancer diagnosis annually, and MCC serves as the DoD's Health Affairs-approved Center of Excellence for cancer care and research for these ADSMs. MCCRP's mission is to bring translational cancer research to all patients in order to improve their health and mission performance, and to help prevent, screen, detect, and treat cancer; minimize side effects of cancer treatments;, and return to duty ADSMs stricken with cancer, as well all other DoD beneficiaries. DoD's Cancer Moonshot initiative allows for the provision of state-of-the-art molecular analysis of tumors and blood of cancer patients which will result in increased force readiness through more targeted treatment of cancers with fewer side effects, as well as better screening for cancer risk and development.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: DoD Cancer Moonshot - Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)	18.640	18.724	19.058	0.000	19.058
Description: DoD's Cancer Moonshot at USU's MCCRP 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 MCCRP collection protocol sites (e.g. Walter Reed, NMMC; NMC Portsmouth; NMC San					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 478 / *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total

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 MCCRP's Proteomics Laboratory, as well as other affiliated protein laboratories. The vast molecular data that will be derived from these analyses (in the terabyte 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 now 7 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 = prospectively-collected VA, DoD, and NCI specimens and data for all organ sites, APOLLO 6: Pancreatic Cancer and APOLLO 7 (currently being developed): Testicular Germ Cell Tumors.

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 deidentified 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 2022 Plans:
FY 2022 Plans continue efforts as outlined in FY 2021.

Specifically, the APOLLO project will collect, process, and analyze cancer specimens from patients who have been diagnosed with cancer or at risk for cancer and who are eligible for and have consented to the protocols. All MCCRP tissue source sites will be utilized which include 8 MTFs and MEDCENS in the MHS, as well as 3 VA sites and one civilian site. Active duty service members diagnosed with cancer at these MHS locations will be preferentially prioritized for offers of enrollment in APOLLO in order to make sure the DoD is providing state-of-

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 478 / *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
the-art research and clinical translational care opportunities to our active duty force to maintain and sustain the highest level of Readiness. The program will complete the following tasks: Task 1: Patients will be recruited and consented for this APOLLO protocol after being successfully recruited into and following the established procedures for the protocols: Establishment of a Tissue Repository for the Murtha Cancer Center Biobank (MCCB), Tissue and Blood Library Establishment for Molecular, Biochemical, and Histologic Study of Breast Disease, and Creation of a Blood Library for the Analysis of Blood for Molecular Changes Associated with Breast Disease and Breast Cancer Development. Task 2: Clinical data collection and quality assurance will follow the established procedures for the sample and data collection protocols. In addition, data may be obtained for the APOLLO study from the DoD Central Tumor Registry (OncoLog) or from the electronic medical records of APOLLO study participants. Task 3: Clinical pathologic slide imaging data will be collected for APOLLO study participants. Clinical pathologic slide imaging data will undergo quality assurance and de-identification procedures at WRNMMC and all other enrolling MTFs and MEDCENs. Task 4: Quality assurance and annotation of samples: The Joint Pathology Center (JPC) will continue to serve as the research pathology annotation center for the APOLLO project for the purpose of annotating pathological diagnoses, expanding pathologic characteristics of samples, and reviewing pathology data variables as defined in this protocol. Task 5: Genomic and proteomic profiling of samples will continue to be conducted by The American Genome Center (TAGC) at the USUHS in Bethesda, MD and the Murtha Cancer Center Research Program's Clinical Proteomics Platform (CPP) Consortium associated with the Gynecologic Cancer Center of Excellence (GYN-COE) at Inova Health System in Fairfax, VA and its associated laboratories at Northwestern University in Evanston, IL and Vanderbilt University in Nashville, TN. Task 6: Coded proteogenomic profiling (molecular) and sample sequencing data along with associated coded clinical data will continue to be transferred to an intermediate NCI protected server ("Jamboree site") and/or an NCI-approved government "Wiki" site at the NCI, and ultimately to the Genomic Data Commons (GDC) and Proteomic Data Commons (PDC). This same data will be securely transferred to certain partners who are assisting in performing integrative analyses of complex DNA, RNA, protein, and clinical data sets and/or in developing bioinformatics tools to do the same.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 478 / *Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Task 7: APOLLO 8 (7th Highest Cause of Cancer in Active Duty): Research on Malignant Brain Tumors (REMBRANT) Perform comprehensive neuropathologic examination of the available military glioblastoma (GBM) cases, and any available ante-mortem neurosurgical material for each decedent in the study. Perform genetic and proteomic characterization of the available military GBM cases to investigate potential associations with clinical outcomes. ***FY 2023 Base Plans:*** Continuation of above efforts from FY22. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Pricing adjustment for inflation.					
Accomplishments/Planned Programs Subtotals	18.640	18.724	19.058	0.000	19.058

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
479: *Framingham Longitudinal Study (USUHS)*	14.760	4.920	4.920	5.018	0.000	5.018	5.118	5.220	5.324	5.430	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 ADSMs who are stricken with a new cancer diagnosis annually, and MCC serves as the DoD's Health Affairs-approved Center of Excellence for cancer care and research for these ADSMs. MCC's mission is to bring translational cancer research to all patients in order to improve their health and mission performance, and to help prevent, screen, detect, and treat cancer; minimize side effects of cancer treatments;, and return to duty ADSMs stricken with cancer, as well all other DoD beneficiaries. DoD's Cancer Moonshot initiative allows for the provision of state-of-the-art molecular analysis of tumors and blood of cancer patients which will result in increased force readiness through more targeted treatment of cancers with fewer side effects, as well as better screening for cancer risk and development.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: DoD Cancer Moonshot Program - DoD Framingham Longitudinal Study	4.920	4.920	5.018	0.000	5.018
Description: DoD Framingham is a novel project that is enabled by the blood serum specimens stored at the DoD Serum Repository at the Armed Forces Health Surveillance Branch (AFHSB) in Silver Spring, Maryland. This facility stores blood serum drawn from over 10 million ADSMs who were required to undergo mandatory semiannual blood testing for the last 25 years, resulting in this repository with over 65 million blood serum specimens. MCC tumor registry data, which includes every ADSM who developed cancer while on active duty, is matched to data in the Serum Repository. This allows MCC to identify the blood serum of ADSMs who ultimately develop cancer at key times, i.e., before they had cancer, during their cancer treatment, and after their successful cancer treatment. Four different serum specimens (two before, one during, and one after cancer diagnosis and treatment) from every ADSM who developed certain types of cancer over a ten-year period of time are then sent to the Nation's foremost protein identification (mass spectroscopy) center, i.e., the Pacific Northwest National Laboratory (PNNL) run by the Department of Energy (DOE). This enables identification of the entire proteome circulating in the blood serum of these cancer patients before, during, and after cancer diagnosis. Comparing the proteomes will allow for identification of new protein biomarkers and indicators of treatment response and failure both of individual patients and across all patients with a specific type of cancer.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 479 / *Framingham Longitudinal Study (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
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 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. Significant FY21 Accomplishments: • A 13-protein classifier for early detection of Oropharyngeal Squamous Cell Carcinoma (Framingham 1) has been discovered through the collaboration with PNNL. This discovery indicates that the use of longitudinal samples in the other Framingham studies has significant potential to identify biomarkers for cancer detection and risk stratification. • MCCRP revised Framingham 3 to Melanoma to research the 2nd Highest Cause of Cancer in Active Duty personnel. • Added Framingham 5 = Metastatic bone cancer. • Added Framingham 6 = Pancreatic cancer. • Sent over 1,800 serum samples from the DoDSR to PNNL for discovery-level mass spectrometry analysis and data interpretation 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 2022 Plans:*** FY 2022 plans continue efforts as outlined in FY 2021.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 479 / *Framingham Longitudinal Study (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
The program will perform the following tasks. Task 1: The Department of Defense (DoD) Joint Pathology Center's (JPC) Automated Central Tumor Registry (ACTUR) and OncoLog systems will be queried for patients with identified cancer subject. Task 2: JPC will send the list of approximately 150 identified cancer patients to the AFHSD in order to requisition their sera. Sera from the year of diagnosis, two years pre-diagnosis, four years pre- diagnosis, and two years post-diagnosis will be requisitioned. Each of the 150 patients with identified cancer will be matched by age and sex to 150 controls who were cancer-free for the duration of their active component service, as well as free of autoimmunity, transplant, or immune suppression. Four longitudinal sera samples from each control will be requisitioned to correspond to the time points of the case sera. Task 3: The approximately 150 identified cancer subjects and 150 matched controls, each with up to four longitudinal serum samples for each Framingham project (for a total of about 1,200 serum samples for each Framingham project), will be sent to Pacific Northwest National Laboratory (PNNL) for comprehensive discovery-based quantitative proteomics measurements using the advanced LC-MS/MS platforms established at PNNL. Task 4: Dissemination of data to analysts at the PNNL and in conjunction with Murtha Cancer Center Research Program (MCCRP) at USUHS, who will perform at PNNL statistical analysis by the PNNL Bioinformatics team to examine whether any of the target peptides or group of peptides can be distinguished between the patients and their matched controls for each specific aim of this study. ***FY 2023 Base Plans:*** Continuation of FY22 plans. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Funding remains the same.					
Accomplishments/Planned Programs Subtotals	4.920	4.920	5.018	0.000	5.018

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 479 / *Framingham Longitudinal Study (USUHS)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 499 / *MHS Financial System Acquisition (DHA)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
499: *MHS Financial System Acquisition (DHA)*	39.958	1.971	6.011	6.051	0.000	6.051	6.092	6.143	6.266	6.388	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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: MHS Financial System Acquisition	1.971	6.011	6.051	0.000	6.051
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 2022 Plans:*** Begin GFEB deployment to the Air Force. ***FY 2023 Base Plans:*** Begin GFEB deployment to the Air Force. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Deployment requirements for the Navy go down and shift towards the operation and maintenance. This program may increase in later years pending potential GFEBS deployment to AF and acceleration in existing acquisitions.					
Accomplishments/Planned Programs Subtotals	1.971	6.011	6.051	0.000	6.051

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 499 / *MHS Financial System Acquisition (DHA)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
• BA 3: *PE 0807721 Replacement & Modernization*	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

Acquisition Strategy is to be determined.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 (Army)*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
504: *WRAIR Vaccine Production Facility Research (Army)*	16.152	0.000	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 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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: WRAIR Vaccine Production Facility ***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.	0.000	-	-	-	-
Accomplishments/Planned Programs Subtotals	0.000	-	-	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
506: *Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)*	11.904	11.141	11.385	11.631	0.000	11.631	11.883	12.141	12.384	12.632	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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Health Research for Improved Medical Readiness and Healthcare Delivery	11.141	11.385	11.631	0.000	11.631
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. CHSR FY2021 accomplishments (selected): • COVID-19 Analytics: provided enabling expertise of public health, health systems, disparities, and data analytics to the development of a national tool for tracking hotspots with the White House Office of S&T Policy; synthesized available US self-reported symptom trackers for the DHA; predictive modeling support with the Joint Staff and ARNORTH; and examination of the interplay between the military and civilian health systems in responding to COVID-19. • Other direct support: Government Accountability Office (consultation in study design, methodology, and data access/use for NDAA 2021), OSD-CAPE (examination of surge capacity in civilian healthcare system), OSD(HA) (Application of Kotter’s 8 Principles of Change Management to transform the MHS), Fisher House Foundation (Future Development of Intrepid Spirit Centers by Guard and Reserves), DHA High Reliability Network (push-pull knowledge translation platform), National Intrepid Center of Excellence and OSD(HA) (Development of an integrated practice unit tool for NICoE and the MHS). • Knowledge translation: High profile work on US child health affecting military readiness (doi: 10.1377/hlthaff.2020.00712) was a driving force behind the Congressional Research Service Report “Obesity in the					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
United States and Effects on Military Recruiting' (2020). Body of work on low-value healthcare services in the MHS informed goals of the 2022 National Defense Authorization Act (NDAA), charging • the DHA with eliminating low value procedures from the MHS as well directly impacting change in T5 and in the current TRICARE consideration for reimbursement for Low Back Pain and Vitamin D screening. • Data workshops: Built capacity in the MHS and partner organizes by offering multiple training workshops including: Person-Data Environment (PDE, October 2020), DaVINCI DoD-VA joint clinical intelligence system (January 2021), What's New in the MHS Data Repository (MDR, August 2021), for over 100 nationwide, military and civilian registrants in each virtual workshop. ***FY 2022 Plans:*** FY 2022 Plans: The CGHE Research Division has augmented and refined its GHERI grant distribution process to a point of readiness for ostensible upcoming funding cycles. CGHE plans to maintain such readiness to rapidly deploy CCMD GHE research priorities, scientific and programmatic review processes, and funding distribution mechanisms when authorized. Further, the CGHE Research Division plans to hold and facilitate a GHE research presentation and poster session at the upcoming 2022 MHSRS conference in Kissimmee, FL. Findings, recommendations, and process improvements resulting from the FRD and USAFRICOM studies will be generated and submitted during FY22. The Center for Military Precision Health (CMPH, formerly known as PRIMER) mission is to conduct innovative research applying genomic science, discoveries, and precision techniques to enhance the health, readiness and well-being of the Warfighter and DoD beneficiaries. CMPH provides standardized state of the art genome and molecular profiling services, genomic data analysis, and genomic data storage under DoD security and privacy compliance policies, addressing 8 separate DoD requirements across the MHS while also providing education in genomic information and performing clinical implementation research in the field of genomic medicine to inform policy and clinical practice guidelines for use of genomics in the MHS. CPMH enables HHS- and DOD-study subjects to participate in translational genomic research studies for human disease and conditions of posttraumatic stress disorder (PTSD), major depressive disorder, suicide-associated behaviors, cardiovascular disease, lung, prostate, breast and gynecological cancer and other human cancers, traumatic brain injury and dementia and other complex human diseases. To date The American Genome Center at CMPH has completed genomic and transcriptomic profiling on over 115,000 human samples. CMPH also supports the					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Military Cardiovascular Outcomes Research (MiCOR) program to addresses gap areas identified in the Initial Capabilities Document for Cardiovascular Care with the first prospective genomic evaluation of cardiac arrest in the military (GEMINI study). Current collaborations with MICOR in focus areas of sudden death examinations and pharmacogenomics are also active to address preventative measures for solider readiness and health. In response to the COVID-19 pandemic CMPH scientists are collaborating with The National Institute of Allergy and Infectious Diseases (NIAID)and the DOD study EPICC via IDCRP, to provide state of the art molecular profiling and analysis of individuals with COVID related illness. These program projects directly address risk factors and biomarkers for chronic and severe COVID-related health conditions after viral infection in young service members for readiness measures. The Military Women's Health research program The Military Women's Health Research Program (MWHRP) 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 focus on basic, clinical and translational research. The MWHRP research initiatives cover a broad spectrum of methods, including basic, translational, clinical, and/or population science that focus on diseases and disorders of particular relevance to the U.S. military health system and address key interests for the health of women. The MWHRP is a cooperative agreement under the direction of the PIs, Col Candy Wilson and Dr. Joan Wasserman. During this funding period, the MWHRC funded research on developing a comprehensive understanding of the female urinary diversion device (FUDD) available to military women when challenged with varying water and sanitation resources and, on urogenital health. Further, this project will test the utility of three, point-of-care devices packaged in an innovative trial product that contains a urogenital self-test as well as a treatment deployment kit that can be combined with a FUDD to increase prevention through early intervention and treatment of hygiene-related urogenital infections (bacterial vaginosis, vulvovaginal candidiasis, and urinary tract infections). This project is directed by Dr. Elizabeth Kostas-Polston, PI. Additionally, the MWHRP hosted a Women in Combat (WIC) summit that updated the previous USUHS CHAMP supported WIC in 2014 and Military Women's Health Research Conference in 2016. This summit is under the direction of the PI, Col Candy Wilson. The WIC will inform strategic medical research priorities to support military women through the integration of multiple sources of expert opinions and research findings.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Infectious Disease Clinical Research Program designs and executes 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. IDCRP 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. IDCRP FY21 Accomplishments: With the global COVID-19 pandemic starting in late Dec 2019, the Infectious Disease Clinical Research Program (IDCRP) has focused its efforts on therapeutic and prophylactics aimed at COVID-19. Two large scale, multi-site clinical studies were initiated with the COVID-19 focus – Epidemiology, Immunology and Clinical Characteristics of Emerging Infectious Diseases with Pandemic Potential (EPICC-EID) and Adaptive Clinical Trial Execution (ACTT). - The Adaptive COVID-19 Treatment Trial (ACTT) is an adaptive platform trial and MHS-based network capability that evaluated the clinical efficacy of different investigational therapeutics for COVID-19. NIAID/DMID-led effort. 67 US and international sites. DoD sites: USU/IDCRP; MAMC; WRNMMC; NMCSD; BAMC; NMCP; WAMC/Ft. Bragg; TAMC. - ACTT1: concept to publication < 3 months; foundational data supporting EUA (NEJM). ACTT2: completed enrollment 53 days, evidence of clinical benefit of baricitinib (NEJM). ACTT3: completed enrollment 98 days, IFN+RDV vs RDV. ACTT4: completed enrollment – RDV + steroids vs RDV + baricitinib, interim analysis; ACTT4 is the final of the ACTT trials (study close out). IDCRP is evaluating future SARS-CoV-2 therapeutic trial opportunities on a case-by-case basis. Lessons learned included: value of modeling projections to guide enrollment expectations, trial network efficiency (enrollment-to-site ratio). - The Epidemiology, Immunology and Clinical Characteristics of Emerging Infectious Diseases with Pandemic Potential (EPICC-EID) study is an ongoing prospective, longitudinal observational study of MHS beneficiaries involving systematic collection and analysis of clinical, demographic, lab data and clinical specimens. Selected recent progress and findings (7 manuscripts in print or under review, multiple presentations at national meetings; periodic newsletter report to senior leaders): - Assessment of variants of concern (VOC) in the MHS: Delta variants associated with higher viral load, noted to infect pediatric ages. Gamma variants found in vaccine breakthrough cases - Characterization of vaccine breakthrough infections, VOC and non-VOC; live viral shedding noted, hospitalization is rare but symptoms can be significant.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
- Long-term natural immunity: 12-month antibody and T-cell responses are robust; long term antibody response and CD4+ response, but not cytotoxic T cell immunity, correlated with initial illness severity - Vaccine induced immunity: Vaccination after natural infection provides a larger magnitude of IgG response than vaccination or natural infection alone - Thrombotic complications of SARS-CoV-2 in the MHS: Viral load does not predict venous thrombo-embolism (VTE) in COVID-19 cases, whereas classic VTE risk factors do. - Assessment of the frequency and impact of “long COVID” among MHS beneficiaries; symptom persistence to 6 months in a subset of prospectively followed study participants. - - In addition to the COVID focus, several other protocols are underway or in late-stage development to address mitigation strategies for military relevant infectious disease threats: - IDCRP-120 PAIVED, “Pragmatic Assessment of Influenza Vaccine Effectiveness in the DoD”. In this multi-year, open-label, randomized clinical trial, adult DoD beneficiaries are randomized to receive one of the three licensed vaccines and are followed over the season for development of incident, laboratory-confirmed influenza infections. Findings from this study will be used to assist with the selection of the optimal vaccine for the DoD. The trial also includes an immunogenicity substudy developed to compare humoral and cellular responses across vaccine products; year 4 enrollment set to begin. - - IDCRP-123 P4 - The P4 clinical trial will evaluate the efficacy of a prebiotic (Bimuno®), probiotic (Florastor®) and passive immunoprophylaxis (Travelan®) compared to placebo, for maintenance of gut health during short-term deployment and travel. The P4 study will evaluate the efficacy of nutraceuticals in maintaining gut health. The protocol has received external Scientific Review and IRB approval in the US as well as ethical approval in the UK, for this international trial. - - IDCRP-115 Treat TD 2.0 builds on the results of the original TrEAT TD study which compared single high-dose rifaximin (1650 mg) with loperamide to single-dose azithromycin or levofloxacin for treatment of acute watery diarrhea. Although high dose rifaximin was effective, a lower dose of the antibiotic would be optimal due to concerns about cost, potential side-effects, and antibiotic resistance. Therefore, TrEAT TD 2.0 evaluates the efficacy of single-dose rifaximin (550 mg) for treatment of acute watery diarrhea among military personnel deployed overseas compared to single-dose azithromycin (500 mg). This effort will benefit from partnerships					

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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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
with DoD research labs both within and outside CONUS (e.g., NMRC, USU, WRAIR, AFRIMS, USAMRU-K, and NAMRU6) and the UK military for execution of the clinical trial and subsequent translational research efforts. - - IDCRP-127 MAGI, clinical trial supported by NIAID DMID to assess whether the licensed meningococcal vaccine Bexsero can protect against infection with N. gonorrhea (gonorrhea, caused by a bacterium related to N meningitidis, the target of the vaccine). This multicenter, international clinical trial, collaboration between USU/ IDCRP and US academic and international partner sites is open and enrolling subjects. CHSR FY 2022 Goals • Global Burden of Disease in the MHS: use claims data from the MHS Data Repository (MDR) in an epidemiological methods framework to examine the total burden of disease, measured in disability-adjusted life years (DALYs), across civilian and military MHS beneficiaries. The two study aims are: 1) measure and describe the diseases and injuries related to the loss of health in the MHS population; and 2) investigate changes in population-level health status over time. This includes engagement with USU-PRIMER, USU-MICOR and the NIH-National Heart, Lung, and Blood Institute (NIH) to determine the burden of heart disease and heart failure in the MHS, and with the NIH-National Center for Deafness and Communication Disorders to determine the burden of hearing loss and vestibular disorders in the MHS. • Long Term Impacts of Military Health System Response to COVID-19: A Health Services Research Approach to Sustainable Process Improvements					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
• Integrated Practice Unit (IPU) assessment with NICoE: use the NICoE model of co-located, integrated care to develop an IPU tool; determine the model's effectiveness in treating traumatic brain injury (TBI) and its long-term effects; and determine the best care pathways for treating differing clusters of TBI symptoms. • Morale, Manpower, and Medicine with University of Minnesota: assess the relationship between military medicine and military effectiveness, both in morale and as a soft power vs. peer and near-peer competitors. • Continued development of knowledge translation platform to provide push-pull capability for MHS leaders, clinical communities, and others. • Community building through the more than 130 member strong Health Services Research Interest Group and Value Based Care Journal Club, which is formed by intersectional MHS leaders and national public health leaders. • Develop and sustain Data Coordination Center for USU and other researchers needing to work with MHS data sets. • Emerging Priorities as will be determined by NDAA 2022, DHA, OSD(HA), and other Federal agencies • Global Burden of Disease Study • Long Term Impacts of Military Health System Response to COVID-19: A Health Services Research Approach to Sustainable Process Improvements • Capacity building through training and workshops • Community building through the Health Services Research Interest Group and Value Based Care Journal Club • Develop and sustain Data Coordination Center for USU and other researchers needing to work with MHS data sets. 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 Combatant Command 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. CGHE continues to serve in a research monitoring role with ongoing FY16, FY18, and FY19 research programs under the Global Health Engagement Research Initiative (GHERI). ***FY 2023 Base Plans:*** CHSR FY 2023 Goals Continue Efforts as outlined in 2022, including:					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
• Global Burden of Disease Study • Long Term Impacts of Military Health System Response to COVID-19: A Health Services Research Approach to Sustainable Process Improvements • Capacity building through training and workshops • Community building through the Health Services Research Interest Group and Value Based Care Journal Club • Develop and sustain Data Coordination Center for USU and other researchers needing to work with MHS data sets. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Price adjusted for inflation.					
Accomplishments/Planned Programs Subtotals	11.141	11.385	11.631	0.000	11.631

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
507: *Brain Injury and Disease Prevention, Treatment and Research (USUHS)*	13.317	13.583	13.855	14.132	0.000	14.132	14.415	14.703	14.997	15.297	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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Brain Injury and Disease Prevention, Treatment and Research	13.583	13.855	14.132	0.000	14.132

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 prion-related neurodegenerative diseases. 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. Using human brain specimens, CTE has been now shown to qualify as a transmissible tau prion disorder. To date, over 320,000 novel chemical compounds have been tested for their ability to interfere with in vitro tau prion formation. Several active compounds have been identified and using medicinal chemistry, we have attempted to improve their bioavailability and lower toxicity profiles. Such candidate drugs are now being tested for efficacy in animal models of tau prion disorders. Newly developed techniques to identify the presence of tau prions in brain samples have been developed and have now been shown to be efficient and highly sensitive.

In addition to the primary achievement of research objectives, the program educates Federal employees as a benefit to the public they serve through Federal service, through support to civil authorities, and in non-Federal professional and academic collaborations.

FY 2022 Plans:
FY 2022 plans continue efforts as outlined in FY 2021.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
While the COVID-19 pandemic continues to constrain our pace of research, we plan to screen an additional 500,000 chemical compounds for potential effects of tau prion formation. Compounds identified with such properties will undergo medicinal chemistry manipulation to enhance biologic efficacy. The newly developed, highly sensitive tau prion assay techniques will be used on currently available and newly obtained human brain specimens and animal models to identify the presence, distribution and time-course of tau prion involvement of the brain. We will continue to further develop animal models which overexpress human tau and employ these for pathogenesis, infectivity and drug efficacy studies. Animal models to be actively investigated include Tg12099(+/-) rats, hMAPT-KI mice, and ferrets. Recognizing the realities of working in the COVID era, activities towards obtaining fresh frozen brain specimens from deceased Service Members who developed CTE will be cautiously expanded in order to provide additional isolates in order to better characterize the nature of tau prions associated with this condition. ***FY 2023 Base Plans:*** Continue plans as outlined in FY 2022 ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Price adjustment for inflation.					
Accomplishments/Planned Programs Subtotals	13.583	13.855	14.132	0.000	14.132

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
508: *Psychological Health and Resilience (USUHS)*	7.000	7.140	7.283	7.428	0.000	7.428	7.577	7.729	7.884	8.042	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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Psychological Health and Resilience	7.140	7.283	7.428	0.000	7.428
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. FY21 Accomplishments: 1. Started data collection of next wave (wave 3) of follow-up data from the STARRS-LS cohort of more than 14,500 Soldiers, including those who have left the Army and transitioned to civilian life. 2. Published six articles in peer-reviewed scientific journals 3. Conducted state-of-the art analyses, including machine-learning predictive models for several outcomes including suicidal behavior of the Army STARRS and STARRS-LS data and produced actionable findings for the Army and DoD ***FY 2022 Plans:*** FY 2022 plans continue efforts as outlined in FY 2021.					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
In addition to the primary achievement of research objectives, the program educates Federal employees as a benefit to the public they serve through Federal service, through support to civil authorities, and in non-Federal professional and academic collaborations. ***FY 2023 Base Plans:*** Continue efforts as outlined in FY 2021 and FY 2022. ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Price adjustment for inflation.					
Accomplishments/Planned Programs Subtotals	7.140	7.283	7.428	0.000	7.428

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
509: *Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)*	19.323	13.712	14.104	14.505	0.000	14.505	14.916	15.334	15.641	15.954	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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness	13.712	14.104	14.505	0.000	14.505
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					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
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 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. Musculoskeletal injuries (MSI) are the largest source of disability in the military and affect 800,000 Service Members annually, accounting for 25 million days of limited duty. Most concerning, the disability discharge rate for MSI has increased 13x between 1981 and 2005 (70 vs. 950 per 100,000 persons), and these trends have continued to increase in the Department of Defense (DoD) and Veterans Affairs Administration in the most recent decade. The Defense Health Agency recognized this unmet clinical/operational gap and funded the formation of the Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR) organization in 2019. In the past two years since our inception, MIRROR has established a world-class infrastructure (data, regulatory, governance) that is compliant with the DoD for conducting research, expanded the number of studies from 14 to 37, formed partnerships with 24 military and academic centers, received $55 million in grant funding (with 10 applications pending for approximately $5 million), hosted 5 educational symposiums, generated 18 Post-Operative Rehabilitation Protocols to standardized care across the Tri-Service, and published 26 abstracts and 17 peer-reviewed publications. Furthermore, in order to ensure the safety/ health of our Service Members and research subjects, we donated COVID-19 antibody kits which allowed us to achieve enrollment over 2100 subjects. Moving forward, we plan to executed on our current projects and continue to provide value through: (1) new research and operational support to new military treatment facilities, (2) close critical care injury/pain gaps (e.g., spine, knee, ankle, shoulder), evaluate novel imaging modalities (e.g., elastography), performing sub analyses to understand gender disparities, predisposition to injury, response to treatments, etc. MIRROR was also selected to host a 3-hour session at MHSRS since we received 5% of the abstracts, but this event was unfortunately canceled. The Photomedicine to Enhance Military Readiness program is a four-year, $22 million initiative with the Wellman Institute, DJO, Geneva Foundation, HJF, and Spaulding Rehabilitation. These teams are executing 9 clinical and translational research projects to deliver optimal dosimetry of photobiological therapy to enhance performance, reduce the potential for musculoskeletal injury, assist with nerve graft healing, enhance audiology function, etc. Projects are progressing and in various stages of device development, benchtop research, and regulatory review (Institutional Review Board (IRB) approval for clinical trials and Institutional Care and Use Committee					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
(IACUC) approval for animal research). The team had 3 abstracts accepted to MHSRS and we continue to work on peripheral nerve repair and 3D collagen printing as a natural biomaterial. In addition these clinical and translational research projects, CRSR continues to provide leadership and coordination of the Military Treatment Facility Engagement Committee (MTFEC) within the Pain Management Collaboratory (PMC) Coordinating Center (PMC3), which is an $81 million inter-agency initiative to support a multi-component research effort focused on non-pharmacological approaches for pain management. Four ongoing pragmatic trials studying non-pharmacological approaches to pain for military service members and veterans have accomplished their stated milestones and in the process have provided feedback to DHA on improved policies and procedures to enhance clinical research execution within the DoD. CRSR has been a leader in the 30 institution NCAA-DoD Concussion Assessment, Research and Education (CARE) Consortium, which includes the Service Academy Longitudinal Outcomes Study (SALTOS). To date recruitment totals over 52,000 participants, including more than 22,000 Service Academy cadets and midshipmen, with just under 9,000 recorded concussions making this the largest study of its kind on the natural history and neurobiology of concussion. In FY21, the CARE Consortium has published 18 peer-reviewed manuscripts, with 17 additional manuscripts currently in review, and completed 12 virtual presentations to disseminate important findings from this cohort. Additional funding has been secured totaling $42.65 million for the longitudinal continuation study, CARE-SALTOS Integrated, which will follow cadets, midshipmen, and NCAA athletes post-graduation to determine intermediate and long-term impacts of concussion on health and military service. CRSR continued to maintain its efforts throughout the COVID-19 pandemic while keeping its subjects and research staff safe. Significant accomplishments during this time are (1) development of a mitigation return to research checklist. This check list, shared locally and nationally, is also followed at all U.S. Service Academies and WRNMMC. (2) Published the “COVID-19 Patient and Caregiver Rehabilitation Recovery Guide”, and distributed to not only families and military units downrange in English and Spanish but internationally to share with their family and friends suffering from the pandemic to allow them to stay mission focused; (3) developed the WRNMMC post-discharge COVID-19 patient registry, telehealth, multidisciplinary holistic intervention; (4) created the COVID-19 survivor peer support group. Notable other accomplishments include: (1) continuation of work through Joint Incentive Funding ($5.4M) between the DoD (USU) and VA (Miami) to miniaturize, optimize and clinically disseminate a wearable sensor augmented tele-rehabilitation tool for service members and veterans with lower limb amputation; (2) a successful large animal model for heterotopic ossification research; (3) Shailly Jariwala, Ph.D. was recognized as one of the internationally selected “Rising Stars of Regenerative Rehabilitation”; (4) two blue light emitting prototypes were developed to be used for mitigating infection after					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
osseointegration of prosthetic limbs; (5) preliminary data suggests that Service Dog Training to augment the rehabilitation of individuals with physical and behavioral health injuries is associated with reduced suicide; (6) MIRROR published new clinical practice guidelines for the DoD, with triservice concurrence to standardize and optimize post-operative rehabilitation interventions following the top 11 orthopaedic musculoskeletal surgeries performed in the DHA. (7) Dr. Paul Pasquina, CRSR Director, was announced as the 2020 recipient of the AMSUS Lifetime Achievement Award. ***FY 2022 Plans:*** FY 2022 plans continue efforts as outlined in FY 2021. ***FY 2023 Base Plans:*** Continue efforts as outlined in FY 2021 ***FY 2023 OCO Plans:*** N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** Price adjustments for inflation.					
Accomplishments/Planned Programs Subtotals	13.712	14.104	14.505	0.000	14.505

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / *Medical Technology Development*	Project (Number/Name) 511 / *Cancer Moonshot Initiatives*	

COST ($ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
511: *Cancer Moonshot Initiatives*	0.000	0.000	0.000	12.300	0.000	12.300	12.500	12.800	13.100	13.400	Continuing	Continuing

A. Mission Description and Budget Item Justification

DoD Cancer Moonshot 2 (CM2) is a mission assigned by the DoD to USU's Murtha Cancer Center Research Program (MCCRP) as a mandate from the White House's federal cancer moonshot part 2 that was initiated in 2022. CM2 is the next generation of the original federal cancer moonshot program initiated in 2016, for which the MCCRP is actively engaged in ongoing cancer studies. The DoD CM2 program will build on DoD's original Moonshot areas of study by enhancing the MCCRP's current initiatives and further utilizing and leveraging DoD's unique and additional capabilities to contribute to advancement of the cancer prevention, diagnosis and treatment goals of CM2. The MCCRP's three new initiatives under the CM2 for DoD include: 1) Cancer Research and Clinical Trial Network; 2) Epidemiology; and 3) DoD Serum Repository Projects.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Cancer Moonshot Initiatives	0.000	0.000	12.300	0.000	12.300
Description: There are three new research areas developed for this new Project under the Cancer Moonshot 2 (CM2) for DoD through USU's MCCRP: 1) Cancer Research and Clinical Trial Network; 2) Epidemiology; and 3) DoD Serum Repository Projects. These three new initiatives will address the federal government / White House's seven stated goals for Cancer Moonshot 2 which are: to diagnose cancer sooner; to prevent cancer; to address inequities; to target the right treatments to the right patients; to speed progress against the most deadly and rare cancers including childhood cancers; to support patients caregivers and survivors; and to learn from all patients. Under these seven new pillars for CM2, the two overall goals per the White House for Cancer Moonshot 2 is to decrease the cancer death rate from cancer by 50% over the next 25 years, and to improve the experience of people and their families living with and surviving cancer. Our DoD Cancer Moonshot 2 initiatives are specifically developed and precisely aligned to address the overall CM2 seven pillars and two goals within the DoD health care system along with our federal partners. MCCRP focus of these projects is for active duty, veterans, and beneficiaries at risk for or with cancer. However, the initiatives and findings will have impact for the nation as a whole as a part of the larger national Cancer Moonshot 2.					
FY 2022 Plans: No funding for FY22 so N/A					
FY 2023 Base Plans:					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 511 / *Cancer Moonshot Initiatives*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
There are three new projects under the Cancer Moonshot 2 (CM2) for DoD through USU's MCCRP: 1) Cancer Research and Clinical Trial Network; 2) Epidemiology; and 3) DoD Serum Repository Projects. The base plans for each of the three are as follows: 1) Cancer Research and Clinical Trial Network: Herein referred to as "the network", this is the foundational element of CM2 as it provides the link between the research protocols, studies, and clinical trials, and the patients who need equitable access to them. It is axiomatic that the best treatment for cancer patients is a clinical trial. Despite knowing that, less than 10% of all cancer patients are enrolled in a clinical trial and there are known inequities with regards to lack of diversity in clinical trial enrollment. While MCCRP has done some limited engagement in this area across the DoD and other federal hospitals for our active duty, veterans, and beneficiaries with cancer, this Task #1 will enable the full build-out, development, and to actualize the vast potential of the DoD health care system and its hospitals as well as partner federal facilities. MCCRP will fully enable, staff, and support the network at our hospitals with appropriate needed resources of all types (e.g., personnel; materiel; protocols including regulatory support; data and sample acquisition and management; analytic functions of all acquired data to create new knowledge and material products to include DoD clinical practice guideline development, recommendations to the DHA Oncology Clinical Community to change evidence-based cancer practices across the network, etc. Funding will be also used to support new and varied research studies and clinical trials well beyond those presently underway. These new network clinical trials will include but not be limited to NCI (National Cancer Institute) trials both intramural (NCI investigator specific trials that hitherto are only available at the Bethesda location but under this initiative we would provide equitable access by DoD cancer patients to these unique and new studies), and extramural (e.g., through the trials of cooperative groups known as Alliance, SWOG, COG (Children's Oncology Group), GOG (GYN Oncology Group, etc). Additionally, MCCRP-specific and developed clinical trials and research studies that are unique to our DoD would be newly developed and/or newly expanded and fully implemented through this new network initiative. 2) Epidemiology: Herein referred to as MCCRP "Epi", this area will develop new and expanded aspects and components of the cancer epidemiology research paradigm of MCCRP. Development of a full, robust, and multi-dimensional cancer epidemiology program for CM2 will result in fullest alignment with the goals and intent of the seven pillars of CM2 and the overall goals of decreasing cancer deaths within the DoD and our patients including active duty (Readiness preservation), veterans, and beneficiaries. To accomplish all of this, MCCRP Epi will have new and expanded missions, capabilities, personnel, database access and computing (data science) capabilities including but not limited to cloud computing support for storage and analytics, for any and all MCCRP CM2 projects as well as intramural cancer research projects. New Epi research will be designed, implemented, and conducted that has DoD-wide implications for improving patient care and outcomes (cancer survival) including but not limited to a RWE (Real World Evidence) data analysis program; a CPG (Clinical					

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 511 / *Cancer Moonshot Initiatives*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Practice Guideline) development program that is focused on the presently untapped use of the vast DoD and TRICARE databases of all types in order to develop new, DoD-specific and DoD-focused cancer practice guidelines that will then be promulgated through the DoD/DHA Oncology Clinical Community (OCC) and across our Network that will have direct and ongoing positive impacts on cancer patients as well as ensuring equity of care experience and outcomes for all DoD patients. All new Epi related research, programs, capabilities and associated needed support will be part of this part of CM2. 3) DoD Serum Repository Projects: Herein referred to the “DoDSR”, this new task will be focused on and responsible for the new, compelling interest in using the world-class DoDSR which contains over 62 million blood serum specimens drawn longitudinally on all active duty service members since the late 1980’s to specifically study and address the questions surrounding the role of various DoD-specific environmental exposures and militarily-relevant cancer and other health risks based on the servicemembers’ MOS (Military Occupational Specialty), deployment history, exposure to unknown and/or uncharacterized risks (e.g., Burn pits; high frequency electromagnetic radiation; environmental and/or workplace toxins to include but not limited to high hydrocarbon fuels, soil toxins; others. New research studies and novel methods will be developed, devised, and used to study thousands of DoDSR specimens from active duty servicemembers with a variety of cancer and health risk factors, and to study the ability of new laboratory technologies and capabilities (e.g., microRNA, DNA methylation, single cell analysis, others, multiple protein and/or amino acid panel analytics, others) to identify new tests for the identification and amelioration of risks to service members and veterans from said exposures. Additionally, this task will fund the development of new research protocols, molecular technologies, and data analytic processes and platforms within the focused area of maximizing the promise of the DoDSR to answer critical research questions surrounding these DoD-specific problems affecting the readiness of the force through their impact on service members. ***FY 2023 OCO Plans:*** No funding for this column so N/A ***FY 2022 to FY 2023 Increase/Decrease Statement:*** This Project overall is a new start in FY 2023 and all elements of this new Project are new and novel in support of the DoD aspect of the federal Cancer Moonshot 2 initiative mandated by the White House in February 2022.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	12.300	0.000	12.300

	FY 2021	FY 2022
Congressional Add: Cancer Moonshot Initiatives (USUHS)	0.000	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency		Date: April 2022
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115DHA / *Medical Technology Development*	**Project (Number/Name)** 511 / *Cancer Moonshot Initiatives*

	FY 2021	FY 2022
FY 2021 Accomplishments: N/A ***FY 2022 Plans:*** N/A		
Congressional Adds Subtotals	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

USU optimizes these research funds to achieve its research objectives, often in partnership and collaboration with funding received from other DoD and interagency sources through Interagency Agreements and inter-service Support Agreements, which may be executed via Federal assistance agreements or contracts.

Exhibit R-2A, RDT&E Project Justification: PB 2023 Defense Health Agency			Date: April 2022
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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
830A: *Deployed Warfighter Protection (Army)*	46.164	0.000	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

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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Title: Deployed Warfighter Protection ***Description:*** The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects.	0.000	-	-	-	-
Accomplishments/Planned Programs Subtotals	0.000	-	-	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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