

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Defense Health Agency										Date: May 2021		
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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
Total Program Element	9,067.680	2,097.085	1,932.465	235.197	-	235.197	-	-	-	-	Continuing	Continuing
300A: CSI - Congressional Special Interests	7,347.005	1,502.654	1,702.215	0.000	-	0.000	-	-	-	-	-	-
238C: Air & Space Austere Environment Patient Care and Transport (AF)	31.358	8.088	11.250	12.675	-	12.675	-	-	-	-	Continuing	Continuing
284B: Air & Space Physiology, Medicine and Human Performance (AF)	26.343	5.633	10.418	11.122	-	11.122	-	-	-	-	Continuing	Continuing
285A: Operational Medicine Research & Development (Budgeted) (AF)	29.889	5.514	0.232	0.000	-	0.000	-	-	-	-	Continuing	Continuing
307B: Air & Space Force Health Protection (AF)	72.572	9.919	10.046	11.463	-	11.463	-	-	-	-	Continuing	Continuing
308B: Expeditionary Medicine Research & Development (Budgeted) (AF)	24.981	4.737	2.623	0.000	-	0.000	-	-	-	-	Continuing	Continuing
309A: Regenerative Medicine (USUHS)	55.997	10.209	10.413	10.621	-	10.621	-	-	-	-	Continuing	Continuing
378B: CoE-Breast Cancer Center of Excellence (USU)	29.556	10.475	10.685	10.898	-	10.898	-	-	-	-	Continuing	Continuing
379B: CoE-Gynecological Cancer Center of Excellence (USU)	25.837	9.158	9.341	9.528	-	9.528	-	-	-	-	Continuing	Continuing
382B: CoE-Pain Center of Excellence (USUHS)	14.103	3.376	1.945	2.014	-	2.014	-	-	-	-	Continuing	Continuing
383A: CoE-Prostate Cancer Center of Excellence (USUHS)	56.993	8.359	8.526	8.696	-	8.696	-	-	-	-	Continuing	Continuing
431A: Underbody Blast Testing (Army)	59.411	9.200	0.000	0.000	-	0.000	-	-	-	-	-	-

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0130: Defense Health Program I BA 2: RDT&E					PE 0603115DHA I Medical Technology Development							
448A: Military HIV Research Program (Army)	38.639	7.877	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
830A: Deployed Warfighter Protection (Army)	39.819	6.345	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
478: Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)	29.003	18.566	18.640	18.724	-	18.724	-	-	-	-	Continuing	Continuing
479: Framingham Longitudinal Study (USUHS)	9.666	4.920	4.920	4.920	-	4.920	-	-	-	-	Continuing	Continuing
499: MHS Financial System Acquisition (DHA)	35.580	15.373	1.971	6.011	-	6.011	-	-	-	-	Continuing	Continuing
381: CoE - Integrative Cardiac Health Care (USUHS)	2.811	3.118	1.680	1.744	-	1.744	-	-	-	-	Continuing	Continuing
504: WRAIR Vaccine Production Facility Research (Army)	8.000	8.152	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
506: Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)	0.000	11.904	11.141	11.385	-	11.385	-	-	-	-	Continuing	Continuing
507: Brain Injury and Disease Prevention, Treatment and Research (USUHS)	0.000	13.317	13.583	13.855	-	13.855	-	-	-	-	Continuing	Continuing
508: Psychological Health and Resilience (USUHS)	0.000	7.000	7.140	7.283	-	7.283	-	-	-	-	Continuing	Continuing
509: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)	0.000	19.323	13.710	14.104	-	14.104	-	-	-	-	Continuing	Continuing
373: GDF - Medical Technology Development	1,130.117	78.868	5.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
373A: GDF - MTD (Combat Casualty Care)	0.000	0.000	11.168	15.736	-	15.736	-	-	-	-	Continuing	Continuing

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373B: GDF - MTD (Military Operational Medicine)	0.000	0.000	23.255	19.046	-	19.046	-	-	-	-	Continuing	Continuing	
373C: GDF - MTD (Medical Simulation & Training/Health Informatics)	0.000	0.000	12.613	13.044	-	13.044	-	-	-	-	Continuing	Continuing	
373D: GDF - MTD (Clinical and Rehabilitation Medicine)	0.000	0.000	13.040	14.980	-	14.980	-	-	-	-	Continuing	Continuing	
373E: GDF - MTD (Military Infectious Disease)	0.000	0.000	6.409	6.630	-	6.630	-	-	-	-	Continuing	Continuing	
373F: GDF - MTD (Radiological Health Effects)	0.000	0.000	0.501	0.518	-	0.518	-	-	-	-	Continuing	Continuing	
373G: GDF - MTD (Military Medical Photonics)	0.000	0.000	10.000	10.200	-	10.200	-	-	-	-	Continuing	Continuing	
519: CARES Act - H.R. 748, (P.L. 116-136)	-	315.000	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 Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance.

Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research & Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. 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.

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

For the Army Medical Command -

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

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

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

Three Centers of Excellence (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 (Army) provides evidence-based personalized patient engagement approaches for comprehensive cardiac event prevention through education, outcomes research and technology tools, as well as molecular research to detect cardiovascular disease at an early stage to ultimately discover a signature for cardiovascular health, to find new genes that significantly increase risk for heart attack in Service members and other beneficiaries, and identify molecular markers of obesity and weight loss.

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

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

For the Air Force Medical Service (AFMS), medical research and development programs are divided into five primary thrust areas: En-Route care, Expeditionary Medicine, Operational Medicine (in-garrison care), Force Health Protection (FHP) (detect, prevent, threats), and Human Performance. Expeditionary Medicine is

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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115DHA I <i>Medical Technology Development</i>
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focused on care on the battlefield and in field hospitals prior to transporting patients out of theater to CONUS, and studies trauma resuscitation, hemorrhage control, and other life-saving interventions to keep critically wounded patients alive in the golden hour and to the next level of care. The AFMS is the only service transporting patients on long aeromedical evacuation missions. Therefore, the En-Route care thrust area studies include investigation on the impact of transport on patient and providers (including cabin altitude, noise, vibration, and environmental issues affecting physiology on the aircraft), patient safety factors during transport, medical technologies for use during transport, and research to support education and training with simulation for En-Route care providers. The Human Performance thrust area focuses on optimizing airmen physical and psychological performance, assessing the physical and cognitive demands on the operator (pilot/aircrew), facilitating a safe aviation environment through technology and equipment assessment, and improving/ sustaining airmen performance through training. Medical development and biomedical technology investments in FHP seek to deliver an improved FHP capability across the full spectrum of operations with research that prevents injury/ illness through improved identification and control of health risks. Under FHP, sub-project areas include Occupational Hazard Exposure (Includes Flight Hazards and Integrated Risk), Targeted Risk Identification, Mitigation and Treatment (Formerly Pathogen ID and Novel Therapeutics and includes Big Data), FHP Technologies Development and Assessment (Assay and disease detection), and Health Surveillance, Infection, Injury & Immunity. FHP also includes Innovations and Personalized Medicine. Operational medicine is focused on in garrison care – our next most critical issue post OIF/OEF – and how to care for the whole patient and consideration of comorbidities in treatment of wounded warriors and dependents.

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

B. Program Change Summary (\$ in Millions)	<u>FY 2020</u>	<u>FY 2021</u>	<u>FY 2022 Base</u>	<u>FY 2022 OCO</u>	<u>FY 2022 Total</u>
Previous President's Budget	1,782.072	225.250	235.197	-	235.197
Current President's Budget	2,097.085	1,932.465	235.197	-	235.197
Total Adjustments	315.013	1,707.215	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	315.000	1,707.215			
• Congressional Directed Transfers	-	-			
• Reprogrammings	0.013	-			
• SBIR/STTR Transfer	-	-			

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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115DHA I <i>Medical Technology Development</i>
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Congressional Add Details (\$ in Millions, and Includes General Reductions)	FY 2020	FY 2021
Project: 300A: <i>CSI - Congressional Special Interests</i>		
Congressional Add: 245A - <i>Amyotrophic Lateral Sclerosis (ALS) Research</i>	20.000	40.000
Congressional Add: 293A - <i>Autism Research</i>	15.000	15.000
Congressional Add: 296A - <i>Bone Marrow Failure Disease Research</i>	3.000	7.500
Congressional Add: 310A - <i>Peer-Reviewed Ovarian Cancer Research</i>	35.000	35.000
Congressional Add: 328A - <i>Peer- Reviewed Multiple Sclerosis Research</i>	16.000	20.000
Congressional Add: 335A - <i>Peer-Reviewed Cancer Research</i>	110.000	115.000
Congressional Add: 336A - <i>Peer-Reviewed Lung Cancer Research</i>	14.000	20.000
Congressional Add: 337A - <i>Peer-Reviewed Orthopaedic Research</i>	30.000	30.000
Congressional Add: 338A - <i>Peer-Reviewed Spinal Cord Research</i>	40.000	40.000
Congressional Add: 339A - <i>Peer-Reviewed Vision Research</i>	20.000	20.000
Congressional Add: 352A - <i>Traumatic Brain Injury/Psychological Health Research</i>	106.000	175.000
Congressional Add: 380A - <i>Peer-Reviewed Breast Cancer Research</i>	150.000	150.000
Congressional Add: 390A - <i>Peer-Reviewed Prostate Cancer Research</i>	110.000	110.000
Congressional Add: 392A - <i>Gulf War Illness Peer-Reviewed Research</i>	22.000	22.000
Congressional Add: 396A - <i>Research in Alcohol and Substance Use Disorders</i>	0.000	4.000
Congressional Add: 400A - <i>Peer-Reviewed Medical Research</i>	360.000	370.000
Congressional Add: 417A - <i>Peer-Reviewed Alzheimer Research</i>	15.000	15.000
Congressional Add: 439A - <i>Joint Warfighter Medical Research</i>	30.000	32.000
Congressional Add: 452A - <i>Peer-Reviewed Reconstructive Transplant Research</i>	12.000	12.000
Congressional Add: 454A - <i>Orthotics and Prosthetics Outcomes Research</i>	15.000	15.000
Congressional Add: 456A - <i>HIV/AIDS Program</i>	15.000	16.000
Congressional Add: 459A - <i>Peer-Reviewed Epilepsy Research</i>	12.000	12.000
Congressional Add: 463A – <i>Program Increase: Restore Core Research Funding Reduction (GDF)</i>	185.151	221.215
Congressional Add: 495 - <i>Peer-Reviewed Tick-Borne Disease Research</i>	7.000	7.000
Congressional Add: 496 - <i>Trauma Clinical Research Program</i>	10.000	10.000
Congressional Add: 501 - <i>Peer-Reviewed Hearing Restoration Research (Army)</i>	10.000	10.000

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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115DHA I <i>Medical Technology Development</i>
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Congressional Add Details (\$ in Millions, and Includes General Reductions)	FY 2020	FY 2021
Congressional Add: 502 - <i>CSI - Peer-Reviewed Kidney Cancer Research (Army)</i>	40.000	50.000
Congressional Add: 503 - <i>CSI - Peer-Reviewed Lupus Research (Army)</i>	10.000	10.000
Congressional Add: 540A - <i>Global HIV/AIDS Prevention (Navy)</i>	8.000	8.000
Congressional Add: 660A - <i>Tuberous Sclerosis Complex (TSC)</i>	6.000	8.000
Congressional Add: 790A - <i>Peer-Reviewed Duchenne Muscular Dystrophy</i>	10.000	10.000
Congressional Add: 512 - <i>Peer-Reviewed Melanoma Research</i>	20.000	30.000
Congressional Add: 513 - <i>Chronic Pain Management</i>	15.000	15.000
Congressional Add: 514 - <i>Combat Readiness Medical Research</i>	10.000	10.000
Congressional Add: 515 - <i>Peer-Reviewed Pancreatic Cancer Research</i>	6.000	15.000
Congressional Add: 516 - <i>Peer-Reviewed Rare Cancers Research</i>	7.500	17.500
Congressional Add: 517 - <i>Peer-Reviewed Scleroderma Research</i>	5.000	5.000
Congressional Add: <i>N/a rounding effort</i>	3.003	0.000
Congressional Add Subtotals for Project: 300A	1,502.654	1,702.215
Project: 519: CARES Act - H.R. 748, (P.L. 116-136)		
Congressional Add: <i>CARES Act - H.R. 748, (P.L. 116-136)</i>	315.000	-
Congressional Add Subtotals for Project: 519	315.000	-
Congressional Add Totals for all Projects	1,817.654	1,702.215

Change Summary Explanation

Project 519 was created for CARES Act - H.R. 748, (P.L. 116-136) funding totaling \$315M.

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 300A / CSI - Congressional Special Interests
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COST (\$ in Millions)	Prior Years ⁽⁺⁾	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
300A: CSI - Congressional Special Interests	7,347.005	1,502.654	1,702.215	0.000	-	0.000	-	-	-	-	-	-

⁽⁺⁾ The sum of all Prior Years is \$225.250 million less than the represented total due to several projects ending

A. Mission Description and Budget Item Justification

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

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

	FY 2020	FY 2021
Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research	20.000	40.000
FY 2020 Accomplishments: FY20 Congressional Add		
FY 2021 Plans: FY21 Congressional Add		
Congressional Add: 293A - Autism Research	15.000	15.000
FY 2020 Accomplishments: FY20 Congressional Add		
FY 2021 Plans: FY21 Congressional Add		
Congressional Add: 296A - Bone Marrow Failure Disease Research	3.000	7.500
FY 2020 Accomplishments: FY20 Congressional Add		
FY 2021 Plans: FY20 Congressional Add		
Congressional Add: 310A - Peer-Reviewed Ovarian Cancer Research	35.000	35.000
FY 2020 Accomplishments: FY20 Congressional Add		
FY 2021 Plans: FY21 Congressional Add		
Congressional Add: 328A - Peer-Reviewed Multiple Sclerosis Research	16.000	20.000
FY 2020 Accomplishments: FY20 Congressional Add		
FY 2021 Plans: FY21 Congressional Add		
Congressional Add: 335A - Peer-Reviewed Cancer Research	110.000	115.000

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021
FY 2020 Accomplishments: FY20 Congressional Add		
FY 2021 Plans: FY21 Congressional Add		
Congressional Add: 336A - Peer-Reviewed Lung Cancer Research	14.000	20.000
FY 2020 Accomplishments: FY20 Congressional Add		
FY 2021 Plans: FY21 Congressional Add		
Congressional Add: 337A - Peer-Reviewed Orthopaedic Research	30.000	30.000
FY 2020 Accomplishments: FY20 Congressional Add		
FY 2021 Plans: FY21 Congressional Add		
Congressional Add: 338A - Peer-Reviewed Spinal Cord Research	40.000	40.000
FY 2020 Accomplishments: FY20 Congressional Add		
FY 2021 Plans: FY21 Congressional Add		
Congressional Add: 339A - Peer-Reviewed Vision Research	20.000	20.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 352A - Traumatic Brain Injury/Psychological Health Research	106.000	175.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 380A - Peer-Reviewed Breast Cancer Research	150.000	150.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research	110.000	110.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research	22.000	22.000

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 396A - Research in Alcohol and Substance Use Disorders	0.000	4.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 400A - Peer-Reviewed Medical Research	360.000	370.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 417A - Peer-Reviewed Alzheimer Research	15.000	15.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 439A - Joint Warfighter Medical Research	30.000	32.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research	12.000	12.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research	15.000	15.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 456A - HIV/AIDS Program	15.000	16.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 459A - Peer-Reviewed Epilepsy Research	12.000	12.000

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF)	185.151	221.215
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 495 - Peer-Reviewed Tick-Borne Disease Research	7.000	7.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 496 -Trauma Clinical Research Program	10.000	10.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 501 - Peer-Reviewed Hearing Restoration Research (Army)	10.000	10.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 502 - CSI - Peer-Reviewed Kidney Cancer Research (Army)	40.000	50.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 503 - CSI - Peer-Reviewed Lupus Research (Army)	10.000	10.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 540A - Global HIV/AIDS Prevention (Navy)	8.000	8.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 660A - Tuberous Sclerosis Complex (TSC)	6.000	8.000

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 790A - Peer-Reviewed Duchenne Muscular Dystrophy	10.000	10.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 512 - Peer-Reviewed Melanoma Research	20.000	30.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 513 - Chronic Pain Management	15.000	15.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 514 - Combat Readiness Medical Research	10.000	10.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 515 - Peer-Reviewed Pancreatic Cancer Research	6.000	15.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 516 - Peer-Reviewed Rare Cancers Research	7.500	17.500
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: 517 - Peer-Reviewed Scleroderma Research	5.000	5.000
FY 2020 Accomplishments: Congressional Add		
FY 2021 Plans: Congressional Add		
Congressional Add: N/a rounding effort	3.003	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency	Date: May 2021
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021
<i>FY 2020 Accomplishments:</i> Congressional Add		
<i>FY 2021 Plans:</i> Congressional Add		
Congressional Adds Subtotals	1,502.654	1,702.215

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.

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 238C / <i>Air & Space Austere Environment Patient Care and Transport (AF)</i>			
COST (\$ in Millions)	Prior Years (+)	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
238C: <i>Air & Space Austere Environment Patient Care and Transport (AF)</i>	31.358	8.088	11.250	12.675	-	12.675	-	-	-	-	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)

Title: Air & Space Austere Environment Patient Care and Transport (AF)	FY 2020	FY 2021	FY 2022
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.	8.088	11.250	12.675
FY 2021 Plans: Develop military-relevant models of injury and clinical presentation and evaluate the risks for secondary insult due to transport. Advance therapeutics and novel interventions that mitigate combat casualty care injuries and reduce risks due to transport. Mature technology that reduces size, weight and power, and cold-chain management requirements, and enhances inter-service operability. Model and optimize care provider performance in enroute care operational environments. Continue pursuing the Air Force Medical Service (AFMS) strategic goal A1 to "Transform the Enroute Care System" based on war fighter identified gaps and validated requirements. Analyses will be conducted assessing the critical impact of hypobaria after hemorrhage and resuscitation in a model of hemorrhagic injury.			
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			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency	Date: May 2021
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 238C / <i>Air & Space Austere Environment Patient Care and Transport (AF)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
requirements, as well as continue to optimize labor and resource requirements for future medical combat casualty care operations.			
FY 2021 to FY 2022 Increase/Decrease Statement: Increase is due to inflation.			
Accomplishments/Planned Programs Subtotals	8.088	11.250	12.675

C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
• BA-1, PE 0807714HP: <i>Other Consolidated Health Support</i>	-	-	-	-	-	-	-	-	-		

Remarks
 Accomplishments: Transitioned technology to provide closed-looped control of oxygen delivery, an updated spinal immobilization transport capability, and updated guidance for the Validating Flight Surgeon community regarding the use of Cabin Altitude Restriction prescriptions on Strategic Aeromedical Evacuation. Gained insight on the critical impacts of hypobaric on hemorrhage and resuscitation and progressed in developing countermeasures and treatments for muscle injury and hemorrhagic shock in a hypobaric environment. A life trajectory comparison was performed between psychiatric aeromedical evacuation and non-psychiatric aeromedical evacuation patients to enhance enroute care practices and a targeted analysis of steroid-related metabolites was performed as a method to reduce post-traumatic stress disorder.

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.).

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 284B / <i>Air & Space Physiology, Medicine and Human Performance (AF)</i>			
COST (\$ in Millions)	Prior Years (+)	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
284B: <i>Air & Space Physiology, Medicine and Human Performance (AF)</i>	26.343	5.633	10.418	11.122	-	11.122	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Air & Space Physiology, Medicine and Human Performance (AF)	5.633	10.418	11.122
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 2021 Plans: Continue implementation of the Optimization of Air Force Human Capital research plan focused on medical readiness to support airman mission alignment. Advance understanding of appropriate selection pertaining to new accessions, job placement, injury reduction and retention. Continue assessment and validation of standards across research lines in the areas of vision, psychology, and physiology for high risk and high demand AF career fields, to include those related to unexplained physiological events (UPEs). Develop model to assess and validate performance and risk criteria for individuals within specific career fields.			
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 2021 to FY 2022 Increase/Decrease Statement: Increase is due to inflation			
Accomplishments/Planned Programs Subtotals	5.633	10.418	11.122

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 284B / <i>Air & Space Physiology, Medicine and Human Performance (AF)</i>

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

N/A

Remarks

Accomplishments: Successfully delivered Contract Data Requirements List (CDRL) for the Precision-Based Airmen Optimization (PBAO) Basic Performance Resources (BPR) Inventory in Jan 2020 (6 months ahead of schedule). Successfully completed initial tests involving BPR data collection process across vision, psychologic, physiologic, and audio domains. Also, refined and validated high-level tasks with operational subject matter experts in their respective career fields. Lastly, determined the impact of lower extremity stress fracture on the career trajectories of USAF Basic Military Trainees.

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.).

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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)
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
285A: Operational Medicine Research & Development (Budgeted) (AF)	29.889	5.514	0.232	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 2020	FY 2021	FY 2022
Title: Operational Medicine Research & Development (Budgeted) (AF)	5.514	0.232	-
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 2021 Plans: The current military separation and retirement practices by health care providers will be investigated, including assessment and communication of diabetes risk to separating or retiring members and counseling regarding how to minimize risk. Continued research includes the development of an exportable Diabetes Self-Management Education (DSME) methodology that can be used throughout the Military Health System (MHS) to support national diabetes education and support standards for patient care.			
FY 2021 to FY 2022 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	5.514	0.232	-

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

N/A

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.

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 285A / <i>Operational Medicine Research & Development (Budgeted) (AF)</i>

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.).

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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)
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COST (\$ in Millions)	Prior Years ⁽⁺⁾	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
307B: Air & Space Force Health Protection (AF)	72.572	9.919	10.046	11.463	-	11.463	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Air & Space Force Health Protection (AF)	9.919	10.046	11.463
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 2021 Plans: To detect Airman relative medical threats and stressors using comprehensive monitoring solutions and specific analyte real-time sensing while establishing framework for data automation. These efforts seek to establish solid ground for the transition of relevant models and sensing technologies for advanced prototyping.			
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 2021 to FY 2022 Increase/Decrease Statement: Increase due to inflation			
Accomplishments/Planned Programs Subtotals	9.919	10.046	11.463

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 307B / <i>Air & Space Force Health Protection (AF)</i>

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

Remarks

Accomplishments: Successful decontamination of multiple aircraft in response to COVID-19. Characterization and modeling of airflow on multiple aircraft for optimal cabin air filtering in response to COVID-19. Genetic mutations were evaluated for conferring resistance to infectious diseases; preventive medicine methods were developed for conducting epidemiological queries in training populations; and technologies, therapies, and tools to detect, diagnose, and deter directed energy or radio frequency exposures were evaluated to prevent, preserve, and protect cells.

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.).

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 308B / <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>			
COST (\$ in Millions)	Prior Years (+)	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
308B: <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>	24.981	4.737	2.623	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 2020	FY 2021	FY 2022
Title: Expeditionary Medicine Research & Development (Budgeted) (AF)	4.737	2.623	-
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.			
FY 2021 Plans: Research will continue to evaluate therapies to treat acute non-compressible torso hemorrhage, including Resuscitative Endovascular Balloon Occlusion (REBOA) and the Abdominal Aortic and Junctional Tourniquet (AAJT), a next generation tourniquet. Work will continue on the development of VentRight, which will allow for portable ventilation monitoring. The Autonomous Selective Organ Perfusion (ASOP) platform will be developed for prolonged field and enroute care applications suitable for life and limb salvage technologies.			
FY 2021 to FY 2022 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	4.737	2.623	-

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 308B / <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>

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

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.).

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 309A / <i>Regenerative Medicine (USUHS)</i>			
COST (\$ in Millions)	Prior Years (+)	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
309A: <i>Regenerative Medicine (USUHS)</i>	55.997	10.209	10.413	10.621	-	10.621	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Regenerative Medicine (USUHS)	10.209	10.413	10.621
<p>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.</p> <p>FY 2021 Plans: The Center for Neuroscience and Regenerative Medicine's (CNRM) objectives include: (1) Continue interdisciplinary, collaborative studies that bring together expertise across the Uniformed Services University (USU), the Walter Reed National Military Medical Center (WRNMMC), and the National Institutes of Health (NIH) to perform the highest priority traumatic brain injury (TBI) research, with a particular emphasis in interventional trials in animals and humans, that studies military-related TBI and its comorbidities; (2) Continue operational capability of all Cores to provide efficient research infrastructure with high quality resources and technical expertise; (3) Continued development of the Clinical Trials Unit and expand clinical research capability to increase the number of interventional trials; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY21 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host virtual CNRM Retreat and internal data discussions to foster cross-fertilization of expertise and innovative development across translational and clinical research; (7) Host annual research Symposium to foster interaction among TBI research organizations (postponed due to COVID); (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research; (11) Support fellowship program to facilitate training of the next generation of leaders in military-relevant TBI research and clinical care at three sites (USU, NIH, and University of Maryland's</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 309A / <i>Regenerative Medicine (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
School of Medicine) in the Washington D.C. area; (12) Participation in the development of a unified response to the 01OCT18 Deputy Secretary of Defense memo entitled a "Comprehensive Strategy and Action Plan for Warfighter Brain Health"; (13) Utilize Biospecimen Bank of blood specimens linked to magnetic resonance imaging (MRI) and clinical assessment data in longitudinal studies of TBI patients and relevant comparison cohorts; (14) Creation of work flow pipeline for accurate and efficient analysis of neuroimaging data relevant to TBI, including quantitative analysis of microhemorrhages, traumatic meningeal injury, and white matter abnormalities; (15) Utilize multiple animal models involving multiple species for improved analysis of acute and chronic effects of TBI relevant to the warfighter, including blast exposure, repetitive injury, and stress conditions.			
<i>FY 2022 Plans:</i> FY 2022 plans continue efforts as outlined in FY 2021.			
<i>FY 2021 to FY 2022 Increase/Decrease Statement:</i> Price adjustment for inflation.			
Accomplishments/Planned Programs Subtotals	10.209	10.413	10.621

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2020</u>	<u>FY 2021</u>	<u>FY 2022</u> <u>Base</u>	<u>FY 2022</u> <u>OCO</u>	<u>FY 2022</u> <u>Total</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0806721HP: <i>Uniformed Services University of the Health Sciences</i>	9.840	10.036	10.236	-	10.236	-	-	-	-	-	Continuing Continuing

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

D. Acquisition Strategy
N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 378B / <i>CoE-Breast Cancer Center of Excellence (USU)</i>			
COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
378B: <i>CoE-Breast Cancer Center of Excellence (USU)</i>	29.556	10.475	10.685	10.898	-	10.898	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

	FY 2020	FY 2021	FY 2022
Title: Breast Cancer Center of Excellence	10.475	10.685	10.898
<p>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.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>The Program will complete the following:</p> <p>Objective 1: Identify and consent a minimum of 100 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.</p> <p>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.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 378B / <i>CoE-Breast Cancer Center of Excellence (USU)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>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 (North Carolina), and Puget Sound (Washington). Acquire through consented protocol acquisitions, over 5,000 specimens annually (neo-plastic and non-neoplastic breast tissues and tumors, lymph nodes, metastatic deposits, blood and its components, bone marrow) on patients with all types of breast diseases and cancer with a new focus on veterans and being able to then look at any relationship between deployment history, environmental exposures, and their service record.</p> <p>Objective 4: Bank these biospecimens in the USU MCCRPs BC-COE Biorepository as the substrate for all molecular analyses carried out in USU MCCRPs BC-COE labs, as outlined in the USU MCCRPs BC-COE Core Protocols. Utilize this repository as the basis for intramural and extramural collaborations for secondary usage research.</p> <p>Objective 5: Because of the 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.</p> <p>Objective 6: Conduct integrative profiling research, for protein-expression based, clinically relevant breast cancer stratification.</p> <p>Objective 7: Breast cancer studies focused on two special patients groups bearing poor outcomes, who are enriched in the military active-duty military population: young women, and African American women.</p> <p>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.</p> <p>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 life style factors as well as comorbidities.</p> <p>Objective 10: Breast cancer HER2 Targeted Therapy Optimization</p> <p>Objective 11: With the new addition of VA hospital sites for breast tissue collections and clinical data collation under research protocols, create an informatics infrastructure system to support these new needs of BC-COE research.</p> <p>Objective 12: Analysis of the publicly available TCGA, CPTAC, and other large scale cancer study datasets.</p> <p>FY 2022 Plans: FY 2022 plans continue efforts as outlined in FY 2021.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Pricing adjustment for inflation.</p>			
Accomplishments/Planned Programs Subtotals	10.475	10.685	10.898

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 378B / <i>CoE-Breast Cancer Center of Excellence (USU)</i>

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

N/A

Remarks

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 379B / <i>CoE-Gynecological Cancer Center of Excellence (USU)</i>			
COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
379B: <i>CoE-Gynecological Cancer Center of Excellence (USU)</i>	25.837	9.158	9.341	9.528	-	9.528	-	-	-	-	Continuing	Continuing

Note

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

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 2020	FY 2021	FY 2022
Title: Gynecological Cancer Center of Excellence	9.158	9.341	9.528

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 379B / <i>CoE-Gynecological Cancer Center of Excellence (USU)</i>

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

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 2021 Plans:

Develop novel strategies for prevention, early detection, and precision treatment of gynecologic cancers by identifying molecular alterations in these diseases. Interrogate ovarian and uterine cancer looking at the complex interplay of tumor cells and the surrounding stroma that supports carcinogenesis as well as the molecular landscape of primary versus metastatic disease. These investigations will facilitate development of clinical biomarkers and assays for gynecologic malignancies throughout the spectrum of care and improve early diagnosis and clinical care.

FY 2022 Plans:

FY 2020	FY 2021	FY 2022

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 379B / <i>CoE-Gynecological Cancer Center of Excellence (USU)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
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 to reveal clinically actionable data to improve outcomes. FY 2021 to FY 2022 Increase/Decrease Statement: Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	9.158	9.341	9.528

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.

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
382B: CoE-Pain Center of Excellence (USUHS)	14.103	3.376	1.945	2.014	-	2.014	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Pain Center of Excellence (USUHS)	3.376	1.945	2.014
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.			
FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. The DVCIPM has developed a 5-year plan for FY20-24 that will focus on further developing the Pain Registry Biobank (PRBioBank) as novel, innovative Institutional Review Board (IRB)-approved registry that combines patient reported outcomes (PASTOR) with blood and tissue samples and other objective measures from participants and Health Services Research and Predictive Modeling. DVCIPM will continue to focus on assimilating complementary and integrative pain management (CIPM), novel analgesics, and interventional pain management. Critical to the continued transformation of DoD pain management, DVCIPM will continue to serve as the MHS's coordinating organization for pain education, clinical policy and knowledge translation.			
FY 2022 Plans: FY 2022 plans continue efforts as outlined in FY 2021.			
FY 2021 to FY 2022 Increase/Decrease Statement: Pricing adjustment for inflation.			
Accomplishments/Planned Programs Subtotals	3.376	1.945	2.014

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 382B / <i>CoE-Pain Center of Excellence (USUHS)</i>

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

N/A

Remarks

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
383A: <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>	56.993	8.359	8.526	8.696	-	8.696	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

Title: CoE-Prostate Cancer Center of Excellence (USUHS)	FY 2020	FY 2021	FY 2022
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-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.	8.359	8.526	8.696

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p><i>FY 2021 Plans:</i> Leverage long term assets of DoD patient database and biospecimen bank towards delineation of molecular markers to enhance treatment decisions through precision medicine with emphasis on racially diverse patients in equal access military healthcare system. Define prostate cancer prevention strategies by addressing the role of predisposing conditions, military-specific exposures, and genetic components in prostate cancer onset and progression of service members. Lead discoveries of prostate cancer causing genes for diagnosing, prognosing and targeted therapy of racially diverse DoD prostate cancer patients with indolent and aggressive disease. Utilize advanced informatics and logistic platforms for enhancing the integration of clinical, biospecimen and molecular database towards the development of diagnostic and prognostic tools.</p> <p><i>FY 2022 Plans:</i> FY 2022 plans continue efforts as outlined in FY 2021.</p> <p><i>FY 2021 to FY 2022 Increase/Decrease Statement:</i> Pricing adjustment for inflation.</p>			
Accomplishments/Planned Programs Subtotals	8.359	8.526	8.696

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
431A: Underbody Blast Testing (Army)	59.411	9.200	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)

Title: Underbody Blast Testing	FY 2020	FY 2021	FY 2022
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.	9.200	-	-
Accomplishments/Planned Programs Subtotals	9.200	-	-

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

N/A

Remarks

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
448A: Military HIV Research Program (Army)	38.639	7.877	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 2020	FY 2021	FY 2022
Title: Military HIV Research Program	7.877	-	-
Description: The Military HIV Research Program aims to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. In addition, program also aims to develop other prevention and treatment strategies to mitigate the HIV epidemic globally. This project down-selects one or more vaccine candidates that are optimized through pre-clinical studies in non-human primates and conducts human clinical trials in Africa, Asia and the U.S. to test for safety and immunogenicity (ability to invoke an immune response), and early proof of concept efficacy testing.			
Accomplishments/Planned Programs Subtotals	7.877	-	-

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

N/A

Remarks

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 448A / <i>Military HIV Research Program (Army)</i>

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.

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 830A / Deployed Warfighter Protection (Army)
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
830A: <i>Deployed Warfighter Protection (Army)</i>	39.819	6.345	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 2020	FY 2021	FY 2022
Title: Deployed Warfighter Protection	6.345	-	-
Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects.			
Accomplishments/Planned Programs Subtotals	6.345	-	-

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.

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 478 / <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
478: <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i>	29.003	18.566	18.640	18.724	-	18.724	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

DoD's Cancer Moonshot requirement is a mission of the Murtha Cancer Center (MCC) at USU under the authority of a tri-federal Memorandum of Agreement signed July 2016 by the Acting Assistant Secretary of Defense for Health Affairs (DoD), the Under Secretary of Health, Department of Veterans Affairs(VHA), and the Acting Director of the National Cancer Institute (NIH), for a tri-federal program of Clinical Proteogenomics Cancer Research. DoD's Cancer Moonshot promotes readiness and mission accomplishment of the active duty service member (ADSM) force, as well as military beneficiaries, retirees, and veterans. There are about 1,000 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 2020	FY 2021	FY 2022
Title: DoD Cancer Moonshot - Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)	18.566	18.640	18.724
Description: 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 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			

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 478 / <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i>

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

	FY 2020	FY 2021	FY 2022
<p>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.</p> <p>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.</p> <p>FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. 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 MCCRPs tissue source sites will be utilized which include 10 MTFs and MEDCENS in the MHS. Active duty service members diagnosed with cancer at these locations will be preferentially prioritized for offers of enrollment in APOLLO in order to make sure the DoD is providing state-of-the-art research and clinical translational care opportunities to our active duty force to maintain and sustain the highest level of Readiness.</p> <p>The program will complete the following tasks:</p> <p>Task 1: Patients will be recruited and consented for this protocol 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.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 478 / <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>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 Automated Central Tumor Registry (ACTUR) or from the electronic medical records of APOLLO study participants.</p> <p>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.</p> <p>Task 4: Quality assurance and annotation of samples: The Joint Pathology Center (JPC) will 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.</p> <p>Task 5: Genomic and proteomic profiling of samples will 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.</p> <p>Task 6: Coded proteogenomic profiling (molecular) and sample sequencing data along with associated coded clinical data will 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.</p> <p>FY 2022 Plans: FY 2022 plans continue efforts as outlined in FY 2021.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Pricing adjustment for inflation.</p>			
Accomplishments/Planned Programs Subtotals	18.566	18.640	18.724

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
479: Framingham Longitudinal Study (USUHS)	9.666	4.920	4.920	4.920	-	4.920	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

DoD Cancer Moonshot Program - DoD Framingham

DoD's Cancer Moonshot requirement is a mission of the Murtha Cancer Center (MCC) at USU under the authority of a tri-federal Memorandum of Agreement signed July 2016 by the Acting Assistant Secretary of Defense for Health Affairs (DoD), the Under Secretary of Health, Department of Veterans Affairs(VHA), and the Acting Director of the National Cancer Institute (NIH), for a tri-federal program of Clinical Proteogenomics Cancer Research. DoD's Cancer Moonshot promotes readiness and mission accomplishment of the active duty service member (ADSM) force, as well as military beneficiaries, retirees, and veterans. There are about 1,000 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 2020	FY 2021	FY 2022
Title: DoD Cancer Moonshot Program - DoD Framingham Longitudinal Study	4.920	4.920	4.920
Description: DoD Framingham is a novel project that is enabled by the blood serum specimens stored at the DoD Serum Repository at the Armed Forces Health Surveillance Branch (AFHSB) in Silver Spring, Maryland. This facility stores blood serum drawn from over 10 million ADSMs who were required to undergo mandatory semiannual blood testing for the last 25 years, resulting in this repository with over 65 million blood serum specimens. MCC tumor registry data, which includes every ADSM who developed cancer while on active duty, is matched to data in the Serum Repository. This allows MCC to identify the blood serum of ADSMs who ultimately develop cancer at key times, i.e., before they had cancer, during their cancer treatment, and after their successful cancer treatment. Four different serum specimens (two before, one during, and one after cancer diagnosis and treatment) from every ADSM who developed certain types of cancer over a ten-year period of time are then sent to the Nation's foremost protein identification (mass spectroscopy) center, i.e., the Pacific Northwest National Laboratory (PNNL) run by the Department of Energy (DOE). This enables identification of the entire proteome circulating in the blood serum of these cancer patients before, during, and after cancer diagnosis. Comparing the proteomes will allow for identification of new protein biomarkers and indicators of treatment response and failure both of individual patients and across all patients with a specific type of cancer. Smaller studies of this nature done by MCC researchers have proven that this is an effective strategy to identify novel diagnostic and treatment protein expression biomarkers that can be assayed in new blood tests for cancer. This			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 479 / <i>Framingham Longitudinal Study (USUHS)</i>

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

	FY 2020	FY 2021	FY 2022
<p>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.</p> <p>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.</p> <p>FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020, including the following tasks: Task 1: The Department of Defense (DoD) Joint Pathology Center’s (JPC) Automated Central Tumor Registry (ACTUR) 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, 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.</p> <p>FY 2022 Plans: FY 2022 plans continue efforts as outlined in FY 2021.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement:</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 479 / <i>Framingham Longitudinal Study (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
Funding remains the same.			
Accomplishments/Planned Programs Subtotals	4.920	4.920	4.920

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
499: MHS Financial System Acquisition (DHA)	35.580	15.373	1.971	6.011	-	6.011	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

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

Title: MHS Financial System Acquisition	FY 2020	FY 2021	FY 2022
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.	15.373	1.971	6.011
FY 2021 Plans: 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.			
FY 2022 Plans: Begin GFEBS deployment to the Air Force.			
FY 2021 to FY 2022 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	15.373	1.971	6.011

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 499 / <i>MHS Financial System Acquisition (DHA)</i>

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

<u>Line Item</u>	<u>FY 2020</u>	<u>FY 2021</u>	<u>FY 2022</u> <u>Base</u>	<u>FY 2022</u> <u>OCO</u>	<u>FY 2022</u> <u>Total</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA 3: <i>PE 0807721</i> <i>Replacement & Modernization</i>	22.611	0.000	0.000	-	0.000	0.000	-	-	-	-	Continuing Continuing

Remarks

D. Acquisition Strategy

Acquisition Strategy is to be determined.

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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)
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
381: CoE - Integrative Cardiac Health Care (USUHS)	2.811	3.118	1.680	1.744	-	1.744	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Integrative Cardiac Health	3.118	1.680	1.744
Description: USU is a “central focal point for health-related education and training, research and scholarship, and leadership support to operational military units around the world” and is the ideal engine to establish a strategic partnership to address cardiovascular health.			
FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. - Complete/continue ongoing projects. - Initiate pivotal randomized clinical trial of 450 Active Duty Service Members for prevention of obesity and cardiovascular outcomes. - Two new registries focused on cardiogenetic care and sudden death in ADSM slated for the FY21.			
FY 2022 Plans: FY 2022 plans continue efforts as outlined in FY 2021.			
FY 2021 to FY 2022 Increase/Decrease Statement: Pricing adjustment for inflation.			
Accomplishments/Planned Programs Subtotals			1.744

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

N/A

Remarks

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 381 / <i>CoE - Integrative Cardiac Health Care (USUHS)</i>

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 504 / <i>WRAIR Vaccine Production Facility Research (Army)</i>			
COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
504: <i>WRAIR Vaccine Production Facility Research (Army)</i>	8.000	8.152	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 2020	FY 2021	FY 2022
Title: WRAIR Vaccine Production Facility	8.152	-	-
Description: The WRAIR Vaccine Pilot Bioproduction Facility (PBF) will focus on the manufacture of early phase clinical materials for vaccine production from varied platforms, such as live virus, conjugates, recombinant proteins, DNA, and monoclonal antibody approaches that: (a) expand collaborative partnerships for product development that meet DoD requirements; (b) open active intramural-based discovery efforts of new products for development; and (c) initiate and extend strategic partnerships with external collaborators (Government and industry) to develop/co-develop potential new biologic approaches to pandemic disease preparedness.			
Accomplishments/Planned Programs Subtotals	8.152	-	-

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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)
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
506: Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)	0.000	11.904	11.141	11.385	-	11.385	-	-	-	-	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 2020	FY 2021	FY 2022
<p>Title: Health Research for Improved Medical Readiness and Healthcare Delivery</p> <p>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.</p> <p>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.</p> <p>The Precision Medicine Initiative for Military Medical Education and Research’s (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. PRIMER provides standardized genome profiling services, genomic data analysis, and genomic data storage under DoD security and privacy compliance policies, addressing 8 separate DoD requirements across the MHS. PRIMER performs clinical implementation research in the field of genomic medicine to inform policy and clinical practice guidelines for use of genomics in the MHS, while also providing education in the use of genomic medicine to health care providers at all levels of training.</p>	11.904	11.141	11.385

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 506 / <i>Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>The military Women’s Health research program mission is to develop and guide best practices for the clinical care of women in the military system, through medical research. This research program will identify priorities that utilize novel and well-defined methods in the areas of personalized medicine and population science and focuses on basic, clinical and translational research.</p> <p>Infectious Disease Clinical Research is multicenter infectious diseases clinical research focusing on high-impact cohorts and interventional trials, to inform and improve care of the Warfighter. The focus is on emerging infections, antimicrobial resistance, and other high priority infections impacting military readiness in US and abroad. It also will generate research evidence to inform warfighter care, develop DoD clinical practice guidance, assess cost effectiveness of interventions, and assist force health protection policy development.</p> <p>FY 2021 Plans: Improve the efficacy of military medical engagements with partner nations in achieving military outcomes for global health. Improve readiness of the Join Force to conduct global health engagement activities in support of geographic combatant commands and national security objectives. Improve quality of tools and capabilities available to commanders for conducting international security cooperation and cooperative health security engagements. Enable single collection site of genomic data for DoD Precision Medicine studies to contribute towards population medicine innovation. Utilize supercomputing infrastructure to support clinical activities. Support research projects in the areas of reproductive health, pain, mental health, cardiovascular disease, cancer, human performance and readiness standards, nutrient and energy requirement for servicewomen.</p> <p>FY 2022 Plans: FY 2022 plans continue efforts as outlined in FY 2021.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Price adjusted for inflation.</p>			
Accomplishments/Planned Programs Subtotals	11.904	11.141	11.385

C. Other Program Funding Summary (\$ in Millions) N/A
Remarks
D. Acquisition Strategy N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
507: Brain Injury and Disease Prevention, Treatment and Research (USUHS)	0.000	13.317	13.583	13.855	-	13.855	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Brain Injury and Disease Prevention, Treatment and Research	13.317	13.583	13.855
<p>Description: Brain Injury and Disease Prevention, Treatment and Research is focused upon identifying drugs that will interfere with pathological tau prion formation in the brains of service members who are at risk for developing CTE and other neurodegenerative diseases following repeated TBI. Service members who have served in combat and have received repeated impact and/or blast TBIs are at risk for developing chronic traumatic encephalopathy (CTE) and other neurodegenerative diseases which are associated with significant persistent behavioral/neurologic manifestations. Currently, there are no validated means for diagnosing these problems in living patients or drugs to effectively treat them. The overall mission of this program is to develop drug candidates that will effectively block the formation of brain tau prions that can be entered into clinical trials for the prevention and/or treatment of CTE and other neurodegenerative disorders in at-risk active duty and retired service members. Using human brain specimens, CTE has been now shown to qualify as a transmissible tau prion disorder. To date, 319,513 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. Part of the progress in this regard is the development of a transgenic rat that overexpresses human tau with the P301S mutation. In addition, new highly sensitive techniques to identify the presence of tau prions in brain samples have been developed.</p> <p>FY 2021 Plans: While the COVID-19 pandemic has constrained our usual pace of research, we hope to continue 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. Newly developed highly sensitive tau prion assay techniques will be used on human specimens and animal models to identify the presence and time-course of tau prion involvement of the brain. Activities towards obtaining fresh frozen brain specimens from Service Members who developed CTE will be maximized in order to better characterize the nature of tau prions associated with this condition.</p> <p>FY 2022 Plans:</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 507 / <i>Brain Injury and Disease Prevention, Treatment and Research (USUHS)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
FY 2022 plans continue efforts as outlined in FY 2021.				
FY 2021 to FY 2022 Increase/Decrease Statement: Price adjustment for inflation.				
Accomplishments/Planned Programs Subtotals		13.317	13.583	13.855
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
D. Acquisition Strategy				
N/A				

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
508: Psychological Health and Resilience (USUHS)	0.000	7.000	7.140	7.283	-	7.283	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Psychological Health and Resilience	7.000	7.140	7.283
Description: STARRS-LS, the longitudinal successor to the groundbreaking Army STARRS research conducted from 2009 to 2015, is the largest study of military suicide ever undertaken, and in addition has yielded a wealth of information about a variety of other health issues relevant to the military. STARRS-LS seeks to extend the original effort by continuing to follow the original participants, expanding the Historical Administrative Data Study and using Big Data techniques to develop knowledge from it, and by combining survey and health outcome data with genetic analyses from samples provided by research participants.			
FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. Specific goals include: 1. Collect the 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. Continue conducting state-of-the art analyses of the Army STARRS and STARRS-LS data and producing actionable findings for the Army and DoD. 3. Continue adapting the data collection and data analyses to meet new and emerging issues identified by the Army and DoD.			
FY 2022 Plans: FY 2022 plans continue efforts as outlined in FY 2021.			
FY 2021 to FY 2022 Increase/Decrease Statement: Price adjustment for inflation.			
Accomplishments/Planned Programs Subtotals	7.000	7.140	7.283

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 508 / <i>Psychological Health and Resilience (USUHS)</i>

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

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
509: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)	0.000	19.323	13.710	14.104	-	14.104	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness	19.323	13.710	14.104
<p>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.</p> <p>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.</p> <p>Rehabilitation Sciences Research supports clinical and translational research efforts dedicated to enhancing the rehabilitative care of the wounded warrior, particularly those with orthopedic trauma, amputation and neurological injury. Research focus areas include: 1) Identifying and mitigating barriers to successful rehabilitation, return to duty and community reintegration; 2) Improved pain management to support active participation in rehabilitation; 3) Applying Advanced Technologies to augment</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 509 / <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
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.			
<i>FY 2021 Plans:</i> Support the advancement of medical technologies such as 1) wearable devices, 2) operational injuries, 3) rehabilitation, 4) precision medicine, and 5) rapid treatment and diagnostics at point of injury. In support of surgical critical care, develop, validate, and/or deploy eleven (11) predictive algorithms for conditions associated with high mortality and morbidity. Support robust medical education and training to ensure the battlefield surgeons of tomorrow are appropriately trained in the use of clinical and biomarker-based CDSTs. Define the optimal rehabilitation strategies and prosthetic selection, fitting and training for wounded warriors with osseointegration. Examine the clinical efficacy of virtual and augmented reality applications to enhance rehabilitation of individuals with extremity dysfunction and acquired brain injury.			
<i>FY 2022 Plans:</i> FY 2022 plans continue efforts as outlined in FY 2021.			
<i>FY 2021 to FY 2022 Increase/Decrease Statement:</i> Price adjustments for inflation.			
Accomplishments/Planned Programs Subtotals	19.323	13.710	14.104

C. Other Program Funding Summary (\$ in Millions) N/A
Remarks
D. Acquisition Strategy N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
373: GDF - Medical Technology Development	1,130.117	78.868	5.000	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 six Joint Program Committees: 1- Medical Simulation and Information Sciences research aims to coordinate health information technology, simulation, and training research across the Military Health System. Technology development efforts are directed toward the medical simulation task. 2- Military Infectious Diseases research is developing protection and treatment products for military relevant infectious diseases. 3- Military Operational Medicine research goals are to develop and validate medical countermeasures against operational stressors, prevent physical and psychological injuries during training and operations, and to maximize health, performance and fitness of Service members. 4- Combat Casualty Care research is optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through en route and facilities care. 5- Radiation Health Effects research focuses on technology development of acute radiation exposure medical countermeasures development. 6- Clinical and Rehabilitative Medicine research is developing knowledge and materiel products to reconstruct, rehabilitate, and provide care for injured Service members. Technology development efforts are directed against tasks in neuromusculoskeletal rehabilitation, pain management, regenerative medicine, and sensory systems.

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

Title: GDF – Medical Technology Development	FY 2020	FY 2021	FY 2022
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.	78.868	5.000	-
FY 2021 Plans: Congressional Add-Restoral			
FY 2021 to FY 2022 Increase/Decrease Statement: Congressional Add-Restoral			
Accomplishments/Planned Programs Subtotals	78.868	5.000	-

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373 / <i>GDF - Medical Technology Development</i>

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

Remarks

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
373A: GDF - MTD (Combat Casualty Care)	0.000	0.000	11.168	15.736	-	15.736	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Medical Technology Development provides funds for the development of promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or human clinical trials regulated by the U. S. Food and Drug Administration prior to licensing for human use. Joint Battlefield Healthcare research is optimizing survival, recovery and rehabilitation in injured Service members across the spectrum of care from point of injury through enroute care and facilities care.

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

	FY 2020	FY 2021	FY 2022
Title: Joint Battlefield Healthcare (Formerly Combat Casualty Care)	-	11.168	15.736
Description: Joint Battlefield Healthcare medical technology development will continue to focus on investigating new diagnostic tools and treatments for prolonged battlefield hemorrhage control, how to best diagnose and treat severe neurotrauma from the point of injury to evacuation/enroute care and long term hospital and rehabilitative care, and research into optimizing the system wide movement of patients to different levels of care to ensure positive clinical outcomes.			
FY 2021 Plans: Joint Battlefield Healthcare medical technology development will continue to focus on investigating new diagnostic tools and treatments for prolonged battlefield hemorrhage control, how to best diagnose and treat severe neurotrauma from the point of injury to evacuation/enroute care and long term hospital and rehabilitative care, and research into optimizing the system wide movement of patients to different levels of care to ensure positive clinical outcomes.			
FY 2022 Plans: Joint Battlefield Healthcare 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 2021 to FY 2022 Increase/Decrease Statement: Increased funding for science and technology activities in patient movement, prolonged field care and enroute care to support medical readiness and return to duty requirements in future operational environments.			
Accomplishments/Planned Programs Subtotals	-	11.168	15.736

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - MTD (Combat Casualty Care)</i>

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
373B: GDF - MTD (Military Operational Medicine)	0.000	0.000	23.255	19.046	-	19.046	-	-	-	-	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 countermeasures against operational stressors, or that prevent musculoskeletal, neurosensory, and psychological injuries during training and from point of injury through role of care four.

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

	FY 2020	FY 2021	FY 2022
Title: Military Health and Recovery (Formerly Military Operational Medicine)	-	23.255	19.046
Description: Efforts focus on: Injury prevention and recovery; Optimized cognition and fatigue management; Psychological health and resilience; and, Performance in extreme environments. Activities 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 2021 Plans: Efforts focus on: Injury prevention and recovery; Optimized cognition and fatigue management; Psychological health and resilience; and, Performance in extreme environments. Activities 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 2022 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 2021 to FY 2022 Increase/Decrease Statement: Decrease due to shifting requirements.			
Accomplishments/Planned Programs Subtotals	-	23.255	19.046

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373B / <i>GDF - MTD (Military Operational Medicine)</i>
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
373C: GDF - MTD (Medical Simulation & Training/Health Informatics)	0.000	0.000	12.613	13.044	-	13.044	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Medical Simulation Technologies (Formerly Medical Simulation Technologies & Training/Health Informatics)	-	12.613	13.044
<p>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.</p> <p>FY 2021 Plans: 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;</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373C / <i>GDF - MTD (Medical Simulation & Training/Health Informatics)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>technologies that simulate combat scenarios to provide realistic environments; and, technologies that simulate patient movement through the continuum of care.</p> <p><i>FY 2022 Plans:</i> Conduct studies, investigations, and non-system specific technology effort focus on prototyping tissue models, technologies that simulate medical condition progress over time, personalized 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, including the brain and all organ systems of the body; 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 -including those anticipated from future weaponry, 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.</p> <p><i>FY 2021 to FY 2022 Increase/Decrease Statement:</i> Increase due to inflation</p>			
Accomplishments/Planned Programs Subtotals	-	12.613	13.044

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
373D: GDF - MTD (Clinical and Rehabilitation Medicine)	0.000	0.000	13.040	14.980	-	14.980	-	-	-	-	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 in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and sensory systems.

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

	FY 2020	FY 2021	FY 2022
Title: Clinical and Rehabilitation Medicine	-	13.040	14.980
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 2021 Plans: 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: Efforts will continue to focus on clinical and rehabilitation medicine to support clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment, and rehabilitation outcomes for Service-related injuries; the development of 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 2021 to FY 2022 Increase/Decrease Statement: Increase supports planned expansion of Artificial Intelligence (AI) application effort for neuromusculoskeletal injury prevention and treatment integration.			
Accomplishments/Planned Programs Subtotals	-	13.040	14.980

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373D / <i>GDF - MTD (Clinical and Rehabilitation Medicine)</i>
C. Other Program Funding Summary (\$ in Millions)		
Remarks		
D. Acquisition Strategy N/A		

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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)
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
373E: GDF - MTD (Military Infectious Disease)	0.000	0.000	6.409	6.630	-	6.630	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Military infectious disease efforts continue to focus on the development of protection and treatment products for military relevant infectious diseases.

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

	FY 2020	FY 2021	FY 2022
<p>Title: Military Infectious Disease</p> <p>Description: Military infectious disease activities to support efforts (including clinical) to develop innovative therapeutics and delivery technologies for combat wound infections. These efforts include Combating Antibiotic Resistant bacteria as well as accelerating promising drug and vaccine solutions to emerging infectious diseases (e.g. chikungunya, MERS, and Zika).</p> <p>FY 2021 Plans: Military infectious disease activities to support efforts (including clinical) to develop innovative therapeutics and delivery technologies for combat wound infections. These efforts include Combating Antibiotic Resistant bacteria as well as accelerating promising drug and vaccine solutions to emerging infectious diseases (e.g. chikungunya, MERS, and Zika).</p> <p>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.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funding change reflects planned lifecycle of this effort.</p>	-	6.409	6.630
Accomplishments/Planned Programs Subtotals	-	6.409	6.630

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

N/A

Remarks

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373E / <i>GDF - MTD (Military Infectious Disease)</i>

D. Acquisition Strategy
N/A

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

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)
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
373F: GDF - MTD (Radiological Health Effects)	0.000	0.000	0.501	0.518	-	0.518	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Research and development in countermeasures for acute radiation exposure leading toward identification of post-exposure treatment of radiation injury. Developing an FDA-approved countermeasure for both pre-exposure prophylaxes and post-exposure treatments of acute radiation syndrome (ARS) will help improve health outcomes for radiation exposure injuries.

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

	FY 2020	FY 2021	FY 2022
Title: Radiological Health Effects	-	0.501	0.518
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 2021 Plans: 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: Continue 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 2021 to FY 2022 Increase/Decrease Statement: Funding change reflects planned lifecycle of this effort.			
Accomplishments/Planned Programs Subtotals	-	0.501	0.518

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

N/A

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373F / <i>GDF - MTD (Radiological Health Effects)</i>

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

Remarks

D. Acquisition Strategy

N/A

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 373G / <i>GDF - MTD (Military Medical Photonics)</i>			
COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
373G: <i>GDF - MTD (Military Medical Photonics)</i>	0.000	0.000	10.000	10.200	-	10.200	-	-	-	-	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 military medical needs 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 development and utilization of optical science and technology for diagnostic, imaging, and therapeutic solutions in support of combat casualty care.

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

	FY 2020	FY 2021	FY 2022
Title: Military Medical Photonics	-	10.000	10.200
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 2021 Plans: 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 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			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373G / <i>GDF - MTD (Military Medical Photonics)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
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 2021 to FY 2022 Increase/Decrease Statement: Funding change reflects planned lifecycle of this effort.				
Accomplishments/Planned Programs Subtotals		-	10.000	10.200
C. Other Program Funding Summary (\$ in Millions) N/A				
Remarks				
D. Acquisition Strategy N/A				

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency **Date:** May 2021

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 519 / CARES Act - H.R. 748, (P.L. 116-136)
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
519: CARES Act - H.R. 748, (P.L. 116-136)	-	315.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

Note
Congressional Add: CARES Act - H.R. 748, (P.L. 116-136)

A. Mission Description and Budget Item Justification
CARES Act - H.R. 748, (P.L. 116-136)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021
Congressional Add: CARES Act - H.R. 748, (P.L. 116-136)	315.000	-
FY 2020 Accomplishments: CARES Act - H.R. 748, (P.L. 116-136)		
Congressional Adds Subtotals	315.000	-

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

Remarks

D. Acquisition Strategy
N/A