

UNCLASSIFIED

| Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency | | | | | | | | | | | Date: February 2020 | |
|--|-------------|-----------|-----------|--------------|---|---------------|---------|---------|---------|---------|---------------------|------------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| Total Program Element | 7,763.338 | 1,594.929 | 1,782.072 | 225.250 | - | 225.250 | 235.197 | 240.220 | 245.344 | 250.580 | Continuing | Continuing |
| 300A: CSI - Congressional Special Interests | 6,018.979 | 1,328.026 | 1,502.651 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - |
| 238C: Enroute Care Research & Development (Budgeted) (AF) | 23.121 | 8.237 | 9.391 | 11.250 | - | 11.250 | 12.675 | 12.866 | 13.122 | 13.387 | Continuing | Continuing |
| 238D: Core Enroute Care R&D - Clinical Translational Focus (AF) | 0.997 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 238E: Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF) | 0.997 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 243A: Medical Development (Lab Support) (Navy) | 164.298 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - |
| 247A: Elimination of Malaria in Southeast Asia (CARB) (Navy) | 5.812 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 5.812 |
| 247B: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy) | 3.782 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 3.782 |
| 284B: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF) | 19.043 | 7.300 | 8.576 | 10.418 | - | 10.418 | 11.122 | 11.471 | 11.700 | 11.934 | Continuing | Continuing |
| 284C: Core Human Performance R&D - Clinical Translational Focus (AF) | 1.003 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 284D: Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF) | 1.002 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 285A: Operational Medicine Research & Development (Budgeted) (AF) | 25.807 | 4.082 | 4.089 | 0.232 | - | 0.232 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

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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 | | | | | | | | |
| 285B: Core Operational Medicine R&D - Clinical Translational Focus (AF) | 0.929 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 285C: Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF) | 0.928 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 307B: Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF) | 65.644 | 6.928 | 8.199 | 10.046 | - | 10.046 | 11.463 | 11.630 | 11.862 | 12.098 | | Continuing | Continuing |
| 307C: Core Force Health Protection R&D - Clinical Translational Focus (AF) | 0.545 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 307D: Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF) | 0.400 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 308B: Expeditionary Medicine Research & Development (Budgeted) (AF) | 20.100 | 4.881 | 3.636 | 2.623 | - | 2.623 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 308C: Core Expeditionary Medicine R&D - Clinical Translational Focus (AF) | 1.503 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 308D: Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF) | 1.502 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 309A: Regenerative Medicine (USUHS) | 47.964 | 8.033 | 10.209 | 10.413 | - | 10.413 | 10.621 | 10.833 | 11.051 | 11.271 | | Continuing | Continuing |
| 378A: CoE-Breast Cancer Center of Excellence (Army) | 39.699 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 378B: CoE-Breast Cancer Center of Excellence (USU) | 19.640 | 9.916 | 10.475 | 10.685 | - | 10.685 | 10.898 | 11.116 | 11.339 | 11.566 | | Continuing | Continuing |

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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 | | | | | | | | |
| 379A: CoE-Gynecological Cancer Center of Excellence (Army) | 34.939 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 379B: CoE-Gynecological Cancer Center of Excellence (USU) | 17.169 | 8.668 | 9.158 | 9.341 | - | 9.341 | 9.528 | 9.719 | 9.913 | 10.111 | | Continuing | Continuing |
| 381A: CoE-Integrative Cardiac Health Care Center of Excellence (Army) | 20.780 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | | Continuing | Continuing |
| 382A: CoE-Pain Center of Excellence (Army) | 6.436 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | | Continuing | Continuing |
| 382B: CoE-Pain Center of Excellence (USUHS) | 10.901 | 3.202 | 3.376 | 1.945 | - | 1.945 | 2.014 | 2.084 | 2.156 | 2.229 | | Continuing | Continuing |
| 383A: CoE-Prostate Cancer Center of Excellence (USUHS) | 49.072 | 7.921 | 8.359 | 8.526 | - | 8.526 | 8.696 | 8.870 | 9.047 | 9.228 | | Continuing | Continuing |
| 398A: CoE-Neuroscience Center of Excellence (USUHS) | 3.679 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - | - |
| 429A: Hard Body Armor Testing (Army) | 1.356 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - | - |
| 431A: Underbody Blast Testing (Army) | 48.611 | 10.800 | 9.200 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - | - |
| 448A: Military HIV Research Program (Army) | 31.454 | 7.185 | 7.877 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | | Continuing | Continuing |
| 830A: Deployed Warfighter Protection (Army) | 34.106 | 5.713 | 6.345 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | | Continuing | Continuing |
| 478: Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS) | 14.766 | 14.237 | 18.556 | 18.640 | - | 18.640 | 18.724 | 19.098 | 19.480 | 19.870 | | Continuing | Continuing |
| 479: Framingham Longitudinal Study (USUHS) | 4.920 | 4.746 | 4.920 | 4.920 | - | 4.920 | 4.920 | 5.018 | 5.118 | 5.220 | | Continuing | Continuing |

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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 | | | | | | | |
| 499: MHS Financial System Acquisition (DHA) | 15.222 | 20.358 | 15.373 | 1.971 | - | 1.971 | 6.011 | 6.051 | 6.092 | 6.143 | Continuing | Continuing |
| 381: CoE - Integrative Cardiac Health Care (USUHS) | 0.000 | 2.811 | 3.118 | 1.680 | - | 1.680 | 1.744 | 1.809 | 1.875 | 1.943 | Continuing | Continuing |
| 504: WRAIR Vaccine Production Facility Research (Army) | 0.000 | 8.000 | 8.152 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 506: Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS) | 0.000 | 0.000 | 11.904 | 11.141 | - | 11.141 | 11.385 | 11.631 | 11.883 | 12.141 | Continuing | Continuing |
| 507: Brain Injury and Disease Prevention, Treatment and Research (USUHS) | 0.000 | 0.000 | 13.317 | 13.583 | - | 13.583 | 13.855 | 14.132 | 14.415 | 14.703 | Continuing | Continuing |
| 508: Psychological Health and Resilience (USUHS) | 0.000 | 0.000 | 7.000 | 7.140 | - | 7.140 | 7.283 | 7.428 | 7.577 | 7.729 | Continuing | Continuing |
| 509: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS) | 0.000 | 0.000 | 19.323 | 13.710 | - | 13.710 | 14.104 | 14.505 | 14.916 | 15.334 | Continuing | Continuing |
| 373: GDF - Medical Technology Development | 1,006.232 | 123.885 | 78.868 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 373A: GDF - MTD (Combat Casualty Care) | - | 0.000 | 0.000 | 11.168 | - | 11.168 | 15.736 | 16.756 | 19.649 | 20.114 | Continuing | Continuing |
| 373B: GDF - MTD (Military Operational Medicine) | - | 0.000 | 0.000 | 23.255 | - | 23.255 | 19.046 | 19.116 | 18.151 | 18.557 | Continuing | Continuing |
| 373C: GDF - MTD (Medical Simulation & Training/Health Informatics) | - | 0.000 | 0.000 | 12.613 | - | 12.613 | 13.044 | 13.339 | 13.637 | 13.942 | Continuing | Continuing |
| 373D: GDF - MTD (Clinical and Rehabilitation Medicine) | - | 0.000 | 0.000 | 13.040 | - | 13.040 | 14.980 | 15.034 | 14.275 | 14.595 | Continuing | Continuing |
| 373E: GDF - MTD (Military Infectious Disease) | - | 0.000 | 0.000 | 6.409 | - | 6.409 | 6.630 | 6.779 | 6.932 | 7.087 | Continuing | Continuing |

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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>Medical Technology Development</i> | | | | | | | |
| 373F: <i>GDF - MTD (Radiological Health Effects)</i> | - | 0.000 | 0.000 | 0.501 | - | 0.501 | 0.518 | 0.531 | 0.542 | 0.554 | Continuing | Continuing |
| 373G: <i>GDF - MTD (Military Medical Photonics)</i> | - | 0.000 | 0.000 | 10.000 | - | 10.000 | 10.200 | 10.404 | 10.612 | 10.824 | 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.

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.

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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 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

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Medicine. Operational medicine is focused on in garrison care – our next most critical issue post OIF/OEF – and how to care for the whole patient and consideration of comorbidities in treatment of wounded warriors and dependents.

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

| B. Program Change Summary (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 1,647.789 | 279.421 | 269.473 | - | 269.473 |
| Current President's Budget | 1,594.929 | 1,782.072 | 225.250 | - | 225.250 |
| Total Adjustments | -52.860 | 1,502.651 | -44.223 | - | -44.223 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | 1,502.651 | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -52.860 | - | | | |
| • Reprogrammings | - | - | -24.223 | - | -24.223 |
| • Directed Reduction | - | - | -20.000 | - | -20.000 |

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

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

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

Congressional Add: 293A - *Autism Research*

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

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

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

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

| | FY 2019 | FY 2020 |
|--|----------------|----------------|
| | 9.665 | 20.000 |
| | 7.248 | 15.000 |
| | 2.899 | 3.000 |
| | 19.329 | 35.000 |
| | 5.799 | 16.000 |
| | 86.951 | 110.000 |

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| Congressional Add Details (\$ in Millions, and Includes General Reductions) | FY 2019 | FY 2020 |
|--|----------------|----------------|
| Congressional Add: 336A - <i>Peer-Reviewed Lung Cancer Research</i> | 13.530 | 14.000 |
| Congressional Add: 337A - <i>Peer-Reviewed Orthopaedic Research</i> | 28.994 | 30.000 |
| Congressional Add: 338A - <i>Peer-Reviewed Spinal Cord Research</i> | 28.994 | 40.000 |
| Congressional Add: 339A - <i>Peer-Reviewed Vision Research</i> | 19.314 | 20.000 |
| Congressional Add: 352A - <i>Traumatic Brain Injury/Psychological Health Research</i> | 96.102 | 106.000 |
| Congressional Add: 380A - <i>Peer-Reviewed Breast Cancer Research</i> | 125.639 | 150.000 |
| Congressional Add: 390A - <i>Peer-Reviewed Prostate Cancer Research</i> | 96.645 | 110.000 |
| Congressional Add: 392A - <i>Gulf War Illness Peer-Reviewed Research</i> | 21.295 | 22.000 |
| Congressional Add: 396A - <i>Research in Alcohol and Substance Use Disorders</i> | 3.866 | 0.000 |
| Congressional Add: 400A - <i>Peer-Reviewed Medical Research</i> | 338.309 | 360.000 |
| Congressional Add: 417A - <i>Peer-Reviewed Alzheimer Research</i> | 14.497 | 15.000 |
| Congressional Add: 439A - <i>Joint Warfighter Medical Research</i> | 26.589 | 30.000 |
| Congressional Add: 452A - <i>Peer-Reviewed Reconstructive Transplant Research</i> | 11.597 | 12.000 |
| Congressional Add: 454A - <i>Orthotics and Prosthetics Outcomes Research</i> | 9.665 | 15.000 |
| Congressional Add: 456A - <i>HIV/AIDS Program</i> | 12.473 | 15.000 |
| Congressional Add: 459A - <i>Peer-Reviewed Epilepsy Research</i> | 7.248 | 12.000 |
| Congressional Add: 463A - <i>Program Increase: Restore Core Research Funding Reduction (GDF)</i> | 242.336 | 188.151 |
| Congressional Add: 495 - <i>Peer-Reviewed Tick-Borne Disease Research</i> | 4.832 | 7.000 |
| Congressional Add: 496 - <i>Trauma Clinical Research Program</i> | 9.665 | 10.000 |
| Congressional Add: 501 - <i>Peer-Reviewed Hearing Restoration Research (Army)</i> | 9.665 | 10.000 |
| Congressional Add: 502 - <i>CSI - Peer-Reviewed Kidney Cancer Research (Army)</i> | 19.314 | 40.000 |
| Congressional Add: 503 - <i>CSI - Peer-Reviewed Lupus Research (Army)</i> | 4.832 | 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> | 5.799 | 6.000 |
| Congressional Add: 790A - <i>Peer-Reviewed Duchenne Muscular Dystrophy</i> | 3.093 | 10.000 |
| Congressional Add: 512 - <i>Peer-Reviewed Melanoma Research</i> | 9.665 | 20.000 |
| Congressional Add: 513 - <i>Chronic Pain Management</i> | 9.665 | 15.000 |

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

| | FY 2019 | FY 2020 |
|--|-----------|-----------|
| Congressional Add: 514 - <i>Combat Readiness Medical Research</i> | 14.512 | 10.000 |
| Congressional Add: 515 - <i>Peer-Reviewed Pancreatic Cancer Research</i> | 0.000 | 6.000 |
| Congressional Add: 516 - <i>Peer-Reviewed Rare Cancers Research</i> | 0.000 | 7.500 |
| Congressional Add: 517 - <i>Peer-Reviewed Scleroderma Research</i> | 0.000 | 5.000 |
| Congressional Add Subtotals for Project: 300A | 1,328.026 | 1,502.651 |
| Congressional Add Totals for all Projects | 1,328.026 | 1,502.651 |

Change Summary Explanation

FY 2021: Programmed effort and funding transferred to other higher priority programs.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | Project (Number/Name) 300A / CSI - Congressional Special Interests | | | | |
|--|-------------|-----------|-----------|--------------|--|---------------|---------|--|---------|---------|------------------|------------|
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 300A: CSI - Congressional Special Interests | 6,018.979 | 1,328.026 | 1,502.651 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - |

A. Mission Description and Budget Item Justification

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

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

| | FY 2019 | FY 2020 |
|---|---------|---------|
| Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research <i>FY 2019 Accomplishments:</i> N/A <i>FY 2020 Plans:</i> N/A | 9.665 | 20.000 |
| Congressional Add: 293A - Autism Research <i>FY 2019 Accomplishments:</i> N/A <i>FY 2020 Plans:</i> N/A | 7.248 | 15.000 |
| Congressional Add: 296A - Bone Marrow Failure Disease Research <i>FY 2019 Accomplishments:</i> N/A <i>FY 2020 Plans:</i> N/A | 2.899 | 3.000 |
| Congressional Add: 310A - Peer-Reviewed Ovarian Cancer Research <i>FY 2019 Accomplishments:</i> N/A <i>FY 2020 Plans:</i> N/A | 19.329 | 35.000 |
| Congressional Add: 328A - Peer- Reviewed Multiple Sclerosis Research <i>FY 2019 Accomplishments:</i> N/A <i>FY 2020 Plans:</i> N/A | 5.799 | 16.000 |
| Congressional Add: 335A - Peer-Reviewed Cancer Research | 86.951 | 110.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 336A - Peer-Reviewed Lung Cancer Research | 13.530 | 14.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 337A - Peer-Reviewed Orthopaedic Research | 28.994 | 30.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 338A - Peer-Reviewed Spinal Cord Research | 28.994 | 40.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 339A - Peer-Reviewed Vision Research | 19.314 | 20.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 352A - Traumatic Brain Injury/Psychological Health Research | 96.102 | 106.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 380A - Peer-Reviewed Breast Cancer Research | 125.639 | 150.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research | 96.645 | 110.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research | 21.295 | 22.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 396A - Research in Alcohol and Substance Use Disorders | 3.866 | 0.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 400A - Peer-Reviewed Medical Research | 338.309 | 360.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 417A - Peer-Reviewed Alzheimer Research | 14.497 | 15.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 439A - Joint Warfighter Medical Research | 26.589 | 30.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research | 11.597 | 12.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research | 9.665 | 15.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 456A - HIV/AIDS Program | 12.473 | 15.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 459A - Peer-Reviewed Epilepsy Research | 7.248 | 12.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF) | 242.336 | 188.151 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 495 - Peer-Reviewed Tick-Borne Disease Research | 4.832 | 7.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 496 -Trauma Clinical Research Program | 9.665 | 10.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 501 - Peer-Reviewed Hearing Restoration Research (Army) | 9.665 | 10.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 502 - CSI - Peer-Reviewed Kidney Cancer Research (Army) | 19.314 | 40.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 503 - CSI - Peer-Reviewed Lupus Research (Army) | 4.832 | 10.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 540A - Global HIV/AIDS Prevention (Navy) | 8.000 | 8.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 660A - Tuberous Sclerosis Complex (TSC) | 5.799 | 6.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 790A - Peer-Reviewed Duchenne Muscular Dystrophy | 3.093 | 10.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 512 - Peer-Reviewed Melanoma Research | 9.665 | 20.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 513 - Chronic Pain Management | 9.665 | 15.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 514 - Combat Readiness Medical Research | 14.512 | 10.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 515 - Peer-Reviewed Pancreatic Cancer Research | 0.000 | 6.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 516 - Peer-Reviewed Rare Cancers Research | 0.000 | 7.500 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 517 - Peer-Reviewed Scleroderma Research | 0.000 | 5.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Adds Subtotals | 1,328.026 | 1,502.651 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |
| 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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | | | | Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 238C: <i>Enroute Care Research & Development (Budgeted) (AF)</i> | 23.121 | 8.237 | 9.391 | 11.250 | - | 11.250 | 12.675 | 12.866 | 13.122 | 13.387 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | | | |
|--|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Enroute Care Research & Development (Budgeted) (AF) | 8.237 | 9.391 | 11.250 |
| Description: This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into products. The sub-project areas include: Impact of Transport on patients and providers (physiological effects of transport factors on patients and crew and impact of transport times on En-Route Trauma and Resuscitative Care), patient safety (includes En-Route data analytics and the optimization of patient care), medical technologies which includes technology advances and clinical assessment at altitude, and research to support En-Route education and training with simulation. | | | |
| FY 2020 Plans: Continue pursuing the AFMS strategic goal A1 to “Transform the En-Route Care System” based on war fighter identified gaps and validated requirements. Begin and/or continue work that will improve mission effectiveness in the A2AD environment such as closed loop technologies and enabling capabilities leading to autonomous patient transport. Plans are to complete multicenter closed-loop ventilation device trials. Continue austere, pre-transport, qualitative clinical testing. Continue to identify independent predictors that are associated with increased survival among patients in a combat theater and update clinical practice and training guidelines to support resulting best practices. Evaluate the influence of altitude, oxygenation, and sedation on neurodegeneration following traumatic brain injury (TBI). Analyses will be conducted assessing the critical impact of hypobaria after hemorrhage and resuscitation. Initiate a retrospective study of patients with traumatic brain injury transported by critical care transport team (CCATT). Assess the effects of aeromedical evacuation on the risk of vasospasm following TBI. Evaluate mechanisms for neuroprotection including hydroxocobalamin in a hemorrhagic model of global and traumatic brain ischemia and to understand and therapeutically target the physiological response associated with prolonged field care and extended hold time. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>Perform service-connected life trajectory comparison of psychiatric aeromedical evacuation and non-psychiatric aeromedical evacuation patients. Studies will evaluate post-traumatic stress disorder reduction using intravenous corticosteroids with analysis of biomarkers using metabolomics. Establish database for medical evacuation treatment indicators with care and resolution outcomes. Discovery, refinement, and implementation of advanced genetics, epigenetics, and transcriptome technologies to predict resiliency and to enhance point-of-care medical and aeromedical decision making.</p> <p>Continue with developing research objectives and end states focused on Clinical En Route Care and Patient Safety; En Route Care Education, Training and Simulation; En Route Care Medical Technologies; Impact of Transport; and Clinical/Patient Decision Support and Monitoring.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020. Analyses will demonstrate the critical impact of hypobaria after hemorrhage and resuscitation.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Increased funding resulting from realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element(PE) 0603115DHA- Medical Technology Development among Project Codes 285A- Operational Medicine Research & Development (AF),308B- Expeditionary Medicine Research & Development (AF),238C- Enroute Care Research & Development (AF), 284B- USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (AF), and 307B- Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (AF) to focus on future readiness mission and operational medical capabilities required to support the warfighter.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 8.237 | 9.391 | 11.250 |

| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | |
|--|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
| • BA-1, PE 0807714HP: <i>Other Consolidated Health Support</i> | - | - | - | - | - | - | - | - | - | - | - |

Remarks

D. Acquisition Strategy

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i> |

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

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|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|---|----------------|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | | | Project (Number/Name) 238D / <i>Core Enroute Care R&D - Clinical Translational Focus (AF)</i> | | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 238D: <i>Core Enroute Care R&D - Clinical Translational Focus (AF)</i> | 0.997 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

D. Acquisition Strategy

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

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|--|----------------|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | Project (Number/Name) 238E / Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF) | | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 238E: Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF) | 0.997 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

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

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 243A / <i>Medical Development (Lab Support) (Navy)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 243A: <i>Medical Development (Lab Support) (Navy)</i> | 164.298 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - |

A. Mission Description and Budget Item Justification

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

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Medical Development (Lab Support) (Navy) | 0.000 | - | - |
| Description: Funding in this project code covers operating and miscellaneous support costs at RDT&E laboratories, including facility, equipment and civilian personnel costs that are not directly chargeable to RDT&E projects. Excluded costs include military manpower and related costs, non-RDT&E base operating costs, and military construction costs, which are included in other appropriate programs. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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| | | | | | | | | | | | | |
|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 247A / Elimination of Malaria in Southeast Asia (CARB) (Navy) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 247A: Elimination of Malaria in Southeast Asia (CARB) (Navy) | 5.812 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 5.812 |

A. Mission Description and Budget Item Justification

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

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

| | | | |
|---|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Elimination of Malaria in Southeast Asia (CARB) (Navy) | 0.000 | - | - |
| Description: This project seeks to demonstrate that malaria can be eliminated in a specific geographically defined area of endemicity through a comprehensive multi-disciplined approach including enhanced surveillance, operations research to maximize the impact of intervention strategies, and quality improvement of current tools for malaria elimination. The demonstration will focus on Vietnam where multi-drug resistant malaria is prevalent and as such represents a significant threat to US personnel. Additionally, the Vietnamese military and Ministry of Health have a high level of interest in malaria control and will collaborate in the malaria elimination demonstration project significantly improving the chances of success of this project. FY 2018 Accomplishments: Enhanced surveillance activities with the Ministry of Health were continued at sites in central Vietnam and on the Laos border. This project has identified risk factors among forest goers, similar to US military personnel in terms of age, health and activity, associated with acquiring malaria. Preliminary data from 2015 and 2016 presented at the American Society of Tropical Medicine and Hygiene (Nov 2016); this information will inform future studies on malaria interventions. To continue work in Vietnam with the Ministry of Health a 2-year work plan was approved in Jul 2016. Continued recruitment of Vietnam-Australia-US military collaborative study to characterize drug resistance in central Vietnam. Preliminary data, indicating no drug resistance present at study site, presented at the USPACOM Asia Pacific Military Health Exchange in Kuantan, Malaysia (Aug 2016). Cross sectional study protocol approved by Vietnam Ministry of Defense; this project started in Q1 FY17 targeting people served by military clinics in Gai Lia Province, a remote area on the Cambodia border. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 247A / <i>Elimination of Malaria in Southeast Asia (CARB) (Navy)</i> |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 247B / Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 247B: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy) | 3.782 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 3.782 |

A. Mission Description and Budget Item Justification

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

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy) | 0.000 | - | - |
| <p>Description: This project seeks to demonstrate that the impact of sepsis from resistant and other high risk organisms in Egypt can be mitigated through the ACESO approach of discovering common, host-based pathogenic pathways for improved recognition and management of sepsis. This project will improve understanding of pathogenesis and antimicrobial resistance mechanisms through network and biomarker analysis to offer unique opportunities for improving sepsis diagnosis and management. Most specifically, ACESO will execute biomarker discovery identifying diagnostic and prognostic biomarker panels which may improve sepsis management in all environments including resourced and austere.</p> <p>FY 2018 Accomplishments: FY 2018 efforts supported continued enrollment of severely ill patients in an observational study in Cambodia at Takeo Provincial Hospital and in Ghana at Komfo Anoyke Teaching Hospital (KATH). The goals of this study are to 1) identify diagnostic and prognostic markers, 2) investigate common pathogenic pathways, 3) describe the spectrum of pathogens causing sepsis,</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 247B / <i>Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>4) describe the treatment strategies currently in use, and 5) assess the long-term sequelae. Adult patients with suspected infection and evidence of systemic inflammation were considered for enrollment. Laboratory testing augmented the testing routinely performed at the hospital microbiology laboratory, and included diagnostic tests (e.g. blood cultures, malaria smears, HIV tests, and serology), molecular diagnostics, and assays measuring the host-response (RNA sequencing, proteomics, and metabolomics). Sophisticated analytic and statistical approaches are being applied to the complex data set to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways.</p> <p>The Vietnam-Australia-US military study of drug resistance patterns in Central Vietnam was closed in Jan 2017 due to a lower than expected malaria burden. Preliminary data supports previous findings, reported in FY16, that there is no resistance for 1st choice malaria drug treatments. Additionally, a review of Vietnam malaria burden, control measures and environmental factors was initiated; the preliminary findings suggest increased average daily temperature was a primary factor of decreased malaria rates. Recruitment for the cross-sectional study in Gai Lia Province (on the border with Cambodia) started in Dec 2016 and was completed in Feb 2017. Sample and data analysis are ongoing, however, preliminary results from the >3,000 participants indicate the rate of patients without symptoms, but still carrying malaria parasite, was >1.25% in this study population, representing a silent malaria transmission risk in this forested, border region on the Cambodia-Vietnam border. The study of Vietnamese workers returning from Africa was initiated in Q2 FY17 with concurrent records review was stated for malaria patients recently returned from Africa presenting for care at two referral medical facilities in Ha Noi in 2014-2016. Preliminary results were accepted for presentation at the Joint International Tropical Medicine Meeting in Bangkok, Thailand from 06-08 Dec 2017. These data suggest delayed malaria clearance in patients returning from Africa was likely due to delayed medical treatment and not from malaria drug resistance.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | | | | Project (Number/Name) 284B / <i>USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 284B: <i>USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)</i> | 19.043 | 7.300 | 8.576 | 10.418 | - | 10.418 | 11.122 | 11.471 | 11.700 | 11.934 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | | | |
|--|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF) | 7.300 | 8.576 | 10.418 |
| Description: This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to Operational and Environmental Challenges to Performance. | | | |
| FY 2020 Plans: | | | |
| Continue implementation of the Optimization of AF Human Capital Research Plan focused on medical readiness to support airman mission alignment. Advance understanding of appropriate selection pertaining to new accessions, job placement, injury reduction and retention. Continue assessment and validation of standards across research lines in the areas of vision, psychology, and physiology for high risk and high demand airman career fields. Develop model to assess and validate return of investment on embedded medics. | | | |
| Work to characterize at risk mission sets and operator/aircrew needs to optimize performance in high altitude environment to inform operational changes and determine safe altitudes for long-term exposures. Advance understanding of neuroprotection and/or neurotreatment therapies designed to mitigate hyperoxemic brain injury/effects. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 284B / <i>USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>Additional studies will examine the influence of lower extremity stress fracture on the career trajectories of USAF Basic Military Trainees.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Increased funding resulting from realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element(PE) 0603115DHA- Medical Technology Development among Project Codes 285A- Operational Medicine Research & Development (AF),308B- Expeditionary Medicine Research & Development (AF),238C- Enroute Care Research & Development (AF), 284B- USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (AF), and 307B- Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (AF)to focus on future readiness mission and operational medical capabilities required to support the warfighter.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 7.300 | 8.576 | 10.418 |

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

N/A

Remarks

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 284C / Core Human Performance R&D - Clinical Translational Focus (AF) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 284C: Core Human Performance R&D - Clinical Translational Focus (AF) | 1.003 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

SEE PROJECT CODE 284B PROGRAM FUNDING SUMMARY FOR PROJECT CODE 284C WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 284D / <i>Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 284D: <i>Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)</i> | 1.002 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

D. Acquisition Strategy

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 285A: <i>Operational Medicine Research & Development (Budgeted) (AF)</i> | 25.807 | 4.082 | 4.089 | 0.232 | - | 0.232 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: Operational Medicine Research & Development (Air Force) | 4.082 | 4.089 | 0.232 |
| Description: The Operational Medicine Thrust Area develops validated solutions for the delivery of preventative care, intervention and treatment to Active Duty members and DoD beneficiaries. The primary focus areas include: physiologic and psychological health; sub-topics include resilience, personalized medicine, patient safety, and care coordination. Basic research initiatives are developed and translated into practice; advanced technology initiatives are focused on prevention and treatment of chronic disease such as obesity and diabetes. Personalized medicine focuses on genomic issues related to autism, asthma, and obesity. | | | |
| FY 2020 Plans: The analysis of genotypes and phenotypes on NIH databases for Air Force precision medicine applications will continue, including the identification of risk factors for pulmonary disorders by associating genomic polymorphisms with pulmonary diseases including asthma, COPD and sarcoidosis. Research will continue on the development of a silica encapsulated dental polymeric material that upon degradation, damage, or fracture, self-repairs the injury. 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. Triggerable release, reloadable, smart hydrogels for graft targeted immunotherapy in reconstructive transplantation will continue to be performed and evaluated. | | | |
| FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020. Research will continue developing diabetes tools, education, and coaching techniques to reduce the cost of patient care and improve outcomes in patients with Type 2 diabetes. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 285A / <i>Operational Medicine Research & Development (Budgeted) (AF)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| Reduced funding due to realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element(PE) 0603115DHA- Medical Technology Development among Project Codes 285A- Operational Medicine Research & Development (AF),308B- Expeditionary Medicine Research & Development (AF),238C- Enroute Care Research & Development (AF), 284B- USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (AF), and 307B- Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (AF)to focus on future readiness mission and operational medical capabilities required to support the warfighter. | | | | |
| Accomplishments/Planned Programs Subtotals | | 4.082 | 4.089 | 0.232 |
| C. Other Program Funding Summary (\$ in Millions) | | | | |
| N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy | | | | |
| Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc.) | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
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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) 285B / <i>Core Operational Medicine R&D - Clinical Translational Focus (AF)</i> | | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 285B: <i>Core Operational Medicine R&D - Clinical Translational Focus (AF)</i> | 0.929 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

SEE PROJECT CODE 285A PROGRAM FUNDING SUMMARY FOR PROJECT CODE 285B WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 285C / <i>Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 285C: <i>Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)</i> | 0.928 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

SEE PROJECT CODE 285A PROGRAM FUNDING SUMMARY FOR PROJECT CODE 285C WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

D. Acquisition Strategy

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 307B / Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 307B: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF) | 65.644 | 6.928 | 8.199 | 10.046 | - | 10.046 | 11.463 | 11.630 | 11.862 | 12.098 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | | | |
|---|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force) | 6.928 | 8.199 | 10.046 |
| Description: This project area seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 307B / <i>Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)</i> |

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <p>stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to detect and identify the USAF- and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need.</p> <p>Recently, research supporting flight line simulations helped guide infrastructure changes at fighter base to accommodate the receipt of aircraft and minimize heat damage to air/ground crews and other jets. Sensors entered into testing to guide methodology for base-level pilot breathing air characterization.</p> <p>FY 2020 Plans: Develop Force and Individual Comprehensive Health Protection System (FInCH) that knows an individual health threat environment and assesses, documents, and informs actions on a real-time basis. Continue study to evaluate breath biomarkers as diagnostic for influenza A. Continue comprehensive evaluation of known naturally occurring genetic variations and experimentally induced mutations in mammalian genes that confer varying degrees of resistance to infectious diseases. A database and software interface will continue to be constructed to allow preventive medicine physicians at training bases to query training population data for epidemiologic purposes. Examine alternate tinnitus management techniques using blood-oxygen-level-dependent MRI with neurofeedback. Evaluate genetic markers for musculoskeletal injuries and ailments. Develop capabilities for remote sensing of environmental hazards. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference. Perform assessment of subtle cognitive and respiratory effects of low-level exposures from low-level exposures in the challenging environments associated with AI operations. Initiate development of automated algorithms that incorporate environmental sensor and risk assessment to determine appropriate mitigation actions in real time as hazards are presented in-flight and in ground operations. Continue early detection, real time prediction of bioenvironmental impact, disease outbreak and intervention, data analytics and information sharing. Continue development and demonstration of the rapid transition of analytics tools that convert a multitude of health related data sources into actionable information based on operational context. Develop a communications platform that can collect exposure and health care data from multiple sources and transmit that data in a compressed format.</p> <p>Additionally, a tiered research plan will be built to address the medical challenges of RF exposure and further validate the clinical guidance and training for clinicians to diagnose and treat greater potential RF weapons insult/injury exposure. The Program will</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 307B / <i>Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>evaluate groundbreaking technologies, therapies and tools to detect, diagnose and deter DE or RFR exposure and to prevent, preserve and protect cells, tissues and organ system functions and homeostasis from the disruptive and damaging effects of directed energy (DE). An MRI and biomarker model for DE exposure will be developed for medical evaluation.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Funding changes reflect a realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element(PE) 0603115DHA- Medical Technology Development among Project Codes 285A- Operational Medicine Research & Development (AF),308B- Expeditionary Medicine Research & Development (AF),238C- Enroute Care Research & Development (AF), 284B- USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (AF), and 307B- Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (AF) to focus on future readiness mission and operational medical capabilities required to support the warfighter.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 6.928 | 8.199 | 10.046 |

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

N/A

Remarks

D. Acquisition Strategy

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 307C / Core Force Health Protection R&D - Clinical Translational Focus (AF) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 307C: Core Force Health Protection R&D - Clinical Translational Focus (AF) | 0.545 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 307D / Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 307D: Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF) | 0.400 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

D. Acquisition Strategy

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 308B: <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i> | 20.100 | 4.881 | 3.636 | 2.623 | - | 2.623 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | | | |
|---|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Expeditionary Medicine Research & Development (Air Force) | 4.881 | 3.636 | 2.623 |
| <p>Description: This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.</p> <p>FY 2020 Plans: Smart polymer-based systems for graft-targeted immunotherapy will continue to be developed to minimize systemic immunosuppression in reconstructive transplantation. Research will continue to evaluate therapies to restore and augment peripheral nerve regeneration and optimize sensory/motor reinnervation for restoration of battlefield injuries applicable to replantation, transplantation, and isolated nerve injuries. Work will continue on the development of VentRight, portable ventilation monitoring combining inline flow, pressure, and CO2 sensors, pulse oximetry, and advanced analytic algorithms for soldiers with respiratory failure, guiding resuscitation by medics or untrained providers in austere conditions or at central MTF.</p> <p>The autonomous selective organ perfusion (ASOP) platform will be evaluated for prolonged field and enroute care applications. Research on the use of intramuscular tranexamic acid (TXA) will continue in a model of hemorrhagic shock and prolonged</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 308B / <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>field care/delayed evacuation. The ability of gold standard and field portable Virtual Reality will continue to improve or augment pain reduction in combat relevant environments. A reproducible protocol for utilizing teleophthalmology will be developed and standardized, assessing the cyber and data security of teleophthalmology devices, and creating a teleophthalmology training program for military ophthalmologists. Methods will be devised and evaluated to capture thrombi due to complications from REBOA treatment. Research will continue to determine if current medical logistic practices need to be reevaluated for storage of medications in high humidity and extreme temperatures used at point-of-injury.</p> <p>FY 2021 Plans: The autonomous selective organ perfusion (ASOP) platform will continue to be evaluated for prolonged field and enroute care applications. Forward operating base ocular trauma telemedicine triage and stabilization will continue. Studies will continue to evaluate strategies to treat occult non-compressible torso hemorrhage.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Reduced funding due to realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element(PE) 0603115DHA- Medical Technology Development among Project Codes 285A- Operational Medicine Research & Development (AF),308B- Expeditionary Medicine Research & Development (AF),238C- Enroute Care Research & Development (AF), 284B- USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (AF), and 307B- Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (AF)to focus on future readiness mission and operational medical capabilities required to support the warfighter.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 4.881 | 3.636 | 2.623 |

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

N/A

Remarks

D. Acquisition Strategy

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
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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) 308C / <i>Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 308C: <i>Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)</i> | 1.503 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

SEE PROJECT CODE 308B PROGRAM FUNDING SUMMARY FOR PROJECT CODE 308C WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 308D / <i>Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 308D: <i>Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)</i> | 1.502 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

SEE PROJECT CODE 308B PROGRAM FUNDING SUMMARY FOR PROJECT CODE 308D WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

D. Acquisition Strategy

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 309A: <i>Regenerative Medicine (USUHS)</i> | 47.964 | 8.033 | 10.209 | 10.413 | - | 10.413 | 10.621 | 10.833 | 11.051 | 11.271 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | | | |
|--|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Regenerative Medicine (USUHS) | 8.033 | 10.209 | 10.413 |
| <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 119 research projects.</p> <p>FY19 Accomplishments:</p> <ul style="list-style-type: none"> - Biorepositories for biomarker analysis of fluids (107,060 specimens) and neuropathology (126 brain donations), specialized for analysis of TBI in Service Members. - Continued hosting of the annual two-day National Capital Area TBI Research Symposium with no registration fees and an average of 400 participants from the Department of Defense, the Department of Health and Human Services, the Department of Veterans Affairs, and local academic institutions to share TBI research advances and to develop collaborative interactions. The Symposium's program development is led by CNRM, with representatives from Johns Hopkins University, University of Maryland, Howard University, Virginia Commonwealth University, the University of Virginia, and Georgetown University. - Continued hosting of the one-day center-wide Retreat attended by approximately 140 persons from CNRM and, also, leadership and staff from ten other TBI research organizations in the Washington D.C. area. The Retreat's purpose is to have CNRM's stakeholders come together to facilitate discussion, networking, and collaboration and, to create an opportunity for CNRM stakeholders to listen to and interact with TBI patients, caregivers, and advocates. - Awarded five (5) new clinical trials: <ol style="list-style-type: none"> 1. Reconsolidation of Traumatic Memories to Resolve Post-Traumatic Stress Disorder 2. Improving sleep in Veterans with TBI: Integrating bright light therapy and blood-based brain biomarkers 3. Mobile Application to Counteract Depression and Concussion 4. Individualized Connectome-targeted rTMS for Depression Associated with Traumatic Brain Injury | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <p>5. Internet Cognitive Behavioral Therapy for TBI-related Insomnia</p> <p>- Awarded three (3) new strategic project cores:</p> <p>1. The Neuropathology-Neuroradiology Integration Core: A partnering of the Neuropathology Core with Dr. Peter Basser’s Section on Quantitative Imaging and Tissue Sciences laboratory at NIH to develop and test novel magnetic resonance imaging (MRI) approaches that could potentially identify TBI-related structural abnormalities in vivo.</p> <p>2. The Translational Therapeutics Core: A state-of-the-science paradigm for the preclinical testing of traumatic brain injury (TBI) treatments intended to alleviate highly relevant post-injury symptoms experienced by Service Members. This core will work to develop a proof-of-concept complex, chronic model of TBI in mice to test the effectiveness of novel treatment options.</p> <p>3. The Optimizing Ferret TBI Experiment: A standardized, complex TBI paradigm in ferrets that incorporates novel pre-and post-injury behavioral tests to evaluate changes in mood, headache, and sleep. Soon, this model will test the efficacy of candidate treatments.</p> <p>- Completion of the deployment of multi-modal forms of advanced imaging technology for diagnosis of TBI, with and without co-morbid PTSD, including MRI-PET, hyperacute MRI, and novel diffusion imaging techniques such as Mean Apparent Propagator.</p> <p>- Expansion of its research agenda to include Operational Research, which focuses on optimizing warfighter brain health in operational environments and consists of two initiatives: Monitoring Blast Exposures and Environmental Overpressure Events, and Prolonged Field Care. These initiatives explore field-based brain health concerns such as blast overpressure exposure, impact/acceleration events, and the development of countermeasures for severe brain injuries, such as subdural hemorrhage, in austere environments.</p> <p>- Continued involvement in the “Comprehensive Strategy and Action Plan for Warfighter Brain Health.” This strategy includes six (6) lines of effort which are: Research, Surveillance and Prevention; Diagnosis, Treatment, Rehabilitation, and Reintegration; Outreach, Education, and Training; Long Term Effects of Traumatic Brain Injury (TBI); and Section 734, NDAA FY 18. The USU will lead three (3) of the Comprehensive Strategy for Warfighter Brain Health’s six (6) lines of effort. These three (3) lines of effort are Research; Long Term Effects of TBI; and Section 734, NDAA FY 18. Our leadership is involved in each of these three (3) lines of effort.</p> <p>- Creation of the USU/NIH Traumatic Brain Injury Research Consortium (TBIRC) to unify, streamline, and ensure visibility of all TBI-related research programs within the USU’s research enterprise. The creation of the TBIRC will enhance the USU’s development and implementation of the initiatives within the “Comprehensive Strategy for Warfighter Brain Health.” Additionally, alignment of the USU’s various TBI research programs with CNRM will allow these programs to benefit from the scientific oversight and expertise of CNRM’s NIH partners. Doing so will, ideally, accelerate progress to the benefit of America’s warfighters and the citizens of the United States.</p> <p>FY 2020 Plans:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>CNRM objectives include: (1) Continue interdisciplinary, collaborative studies that bring together expertise across USU, WRNMMC, and intramural NIH to address the highest priority TBI research in diagnosis through treatment and recovery as relevant to military service members; (2) Continue operational capability of all Cores to provide efficient research infrastructure with high quality resources and technical expertise; (3) Develop Clinical Trials Unit and expand clinical research capability to increase the number of interventional trials ; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY20 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host CNRM retreat and internal data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research;(11) Support fellowship program to facilitate neuroscience and regenerative medicine research capabilities at DoD sites in NCA; (12) Participate on the Traumatic Brain Injury (TBI) Research Synergy Board (RSB) and contribute to the TBI “Unity of Effort” to strategically strengthen and accelerate TBI research on “America’s Health Campus;” (13) Utilize Biospecimen Bank of blood specimens linked to MRI and clinical assessment data in longitudinal studies of TBI patients and relevant comparison cohorts; (14) Brain Tissue Repository of brains donated from military TBI patients, including state-of-the-art neuropathological analysis of blast cases and relevant comparison cohorts; (15) Deployment of multi-modal forms of advanced imaging technology for diagnosis of TBI, with and without co-morbid PTSD, including MRI-PET, hyperacute MRI, and novel diffusion imaging techniques such as Mean Apparent Propagator; (16) Creation of Work flow pipeline for accurate and efficient analysis of neuroimaging data relevant to TBI, including quantitative analysis of microhemorrhages, traumatic meningeal injury, and white matter abnormalities; (17) Utilize multiple animal models involving multiple species for improved analysis of acute and chronic effects of TBI relevant to the warfighter, including blast exposure, repetitive injury, and stress conditions.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Price adjustment.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 8.033 | 10.209 | 10.413 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> | |
|---|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|------------|
| • BA-1, 0806721HP: <i>Uniformed Services University of the Health Sciences</i> | 9.647 | 9.840 | 10.036 | - | 10.036 | 10.236 | - | - | - | - | Continuing | Continuing |

Remarks

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

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 378A / <i>CoE-Breast Cancer Center of Excellence (Army)</i> |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 378A: <i>CoE-Breast Cancer Center of Excellence (Army)</i> | 39.699 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Breast Cancer Center of Excellence | 0.000 | - | - |
| Description: Provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 378B / <i>CoE-Breast Cancer Center of Excellence (USU)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 378B: <i>CoE-Breast Cancer Center of Excellence (USU)</i> | 19.640 | 9.916 | 10.475 | 10.685 | - | 10.685 | 10.898 | 11.116 | 11.339 | 11.566 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Breast Cancer Center of Excellence | 9.916 | 10.475 | 10.685 |
| Description: Breast Cancer CoE provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. | | | |
| <p>FY19 Accomplishments:</p> <ul style="list-style-type: none"> - Accrued hundreds of breast patients to Breast CoE core protocols - Accrued hundreds of breast patients to the ORIEN research protocol - Acquired over 5,000 new biospecimens at our Breast COE sites to the core tissue protocol - Utilized our biospecimens and data base in support of over 20 research studies - Performed critical research on young women with breast cancer, and the demographic of African-American women with breast cancer, key cohorts affecting cancer as a readiness issue for the DoD - Advanced our Immunome project to analysis and prediction model phase - Near completion of our tumor microenvironment component of APOLLO 4 (breast) proteogenomics - Developed additional research work with NCI regarding young women with breast cancer in relation to the active duty component | | | |
| FY 2020 Plans: | | | |
| <p>The Breast Cancer CoE will identify and consent patients (to include patients at high risk for development of breast cancer) annually to the MCC ORIEN research study, with special focus on active duty females as a Force Protection / Readiness sustainment issue to the DoD. Will continue to accrue patients annually to the "core" BC-COE protocols through consenting patients in the main BC-COE clinical sites, with the main site being the Breast Center at the Murtha Cancer Center of Walter Reed NMMC, the military's largest and only NAPBC (National Accreditation Program for Breast Centers) approved breast center in the entire DoD MHS. Will acquire through consented protocol acquisitions, over 5,000 specimens annually (neo-plastic and non-</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>neoplastic breast tissues and tumors, lymph nodes, metastatic deposits, blood and its components, bone marrow) on patients with all types of breast diseases and cancer. Will bank these biospecimens in the BC-COE Biorepository as the substrate for all molecular analyses carried out in BC-COE labs, as outlined in the BC-COE Core Protocols. Will utilize the repository as the basis for intramural and extramural collaborations for secondary usage research. Will continue to conduct integrative profiling research, for protein-expression based, clinically relevant breast cancer stratification on active case IHC assays of a panel of 20 ImmunoHistoChemical (IHA) biomarker and IHC assays of a panel of 27 biomarkers named Connectivity Map EnHigh Density TMA analysis of biomarkers associated with the development of endocrine resistance. Will continue to focus breast cancer studies on two special patients groups bearing poor outcomes, who are enriched in the military active-duty military population: young women, and African American women. Will continue to conduct breast cancer heterogeneity studies, including cellular heterogeneity of tumor development environment and lineage heterogeneity within one physical cancer tumor. Focus areas will be (Breast Cancer Immunome, identification of molecular factors in tumor epithelium and stroma contributing to tumor etiology and breast cancer tumor heterogeneity study through Whole Genome Sequencing. Will conduct studies on mechanistic understanding of breast cancer development from other perspectives, including genetic dispositions, exposure to environmental risks, access to healthcare, and impact of certain life style factors as well as comorbidities. Will continue to conduct breast cancer drug target studies focusing on the triple negative and HER2 subtypes, using 2D and 3D tissue culturing systems and human breast cancer tissues, respectively. Will further develop the informatics infrastructure system to support the evolving needs of Breast Cancer-COE research which will include developing the replacement system for the Clinical Laboratory Workflow System that was implemented years ago, develop and improve data QA programs and SOPs and improve the Data Warehouse for Translational Research by integrating data generated by internal scientists, through collaborations, and those available in the public as needed to facilitate integrative data analysis. The Breast Cancer COE will also continue its Collaborative Translational Research Program. CBCP will fund breast specific collaborative research that addresses problems with translational potential with a focus on environmental factors and the tumor microenvironment. The translational research program will consist of numerous investigators pursuing basic research on breast specific cancer etiology and biology or translational cancer research studies. CBCP will seek to establish support of novel intramural research that has the potential to improve breast cancer outcomes. The goal is to promote collaborative translational research efforts among translational science laboratories at the Clinical Breast Care Project, WRNNMC-MCC, WRI and NCI.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 9.916 | 10.475 | 10.685 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2021 Defense Health Agency **Date:** February 2020

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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) 379A / <i>CoE-Gynecological Cancer Center of Excellence (Army)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 379A: <i>CoE-Gynecological Cancer Center of Excellence (Army)</i> | 34.939 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

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

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Gynecological Cancer Center of Excellence (Army) | 0.000 | - | - |
| Description: The Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecological disease. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

Remarks

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 379B: <i>CoE-Gynecological Cancer Center of Excellence (USU)</i> | 17.169 | 8.668 | 9.158 | 9.341 | - | 9.341 | 9.528 | 9.719 | 9.913 | 10.111 | 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 Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecological disease. The objective of this research is to reduce the incidence, morbidity (illness), and mortality (death) of gynecological diseases among all military beneficiaries.

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

| | | | |
|---|----------------|----------------|----------------|
| Title: Gynecological Cancer Center of Excellence | FY 2019 | FY 2020 | FY 2021 |
| | 8.668 | 9.158 | 9.341 |
| 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. | | | |
| FY19 Accomplishments: | | | |
| - 34 Peer-Reviewed Publications | | | |
| - 16 Invited Lectures / Presentations | | | |
| - 2 Book Chapters | | | |
| - 24 Abstracts presented: | | | |
| SGO 49th Annual Meeting on Women's Cancer® in New Orleans, LA from March 23-27, 2018 (6); American Association for Cancer Research Annual Meeting in Chicago IL from April 14-18, 2018 (2); 66th ASMS Conference, San Diego, CA, June 4-8, 2018 (1); 2018 Military Health System Research Symposium at the Gaylord Convention Center in Kissimmee FL on August 20-23, | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>2018 (5); 2018 American College of Obstetricians and Gynecologists Armed Forces District Meeting in Honolulu, HI in September 2018 (3); SGO 49th Annual Meeting on Women’s Cancer® in Honolulu, HI in March 16-19, 2019 (7).</p> <p>FY 2020 Plans: The FY2020 program will continue to develop novel strategies for prevention, early detection, and precision treatment of gynecologic cancers by identifying molecular alterations in these diseases. We will deeply interrogate ovarian and uterine cancer looking at the complex interplay of tumor cells and the surrounding stroma (or physiologic niche) that supports carcinogenesis (the initiation, progression, and metastatic spread of cancer) as well as the molecular landscape of primary versus metastatic disease. These investigations will facilitate development of clinical biomarkers and assays for gynecologic malignancies throughout the spectrum of care and improve early diagnosis and clinical care. Beyond the above studies, we will continue to build on studies examining molecular determinants of recurrent versus non-recurrent disease and how distribution 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 readiness by earlier detection and prevention of disease in the active duty force and decrease the economic burden of disease in the MHS which his typically diagnosed at late stages and treated without great specificity. We will expand collaborations in investigations of racial and ethnic disparities, risk, outcome, natural history, lifestyle, staging and treatment in cancer including gynecologic malignancies. Under the broad umbrella of outreach and patient reported outcomes research, an overarching goal during this period is to advance patient awareness, education, support and survivorship to improve quality of life, patient experience and mitigate effects. These efforts enhance the experience of care, ensure readiness of the fighting force, and improve beneficiary health adding value while decreasing cost for the Department of Defense.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Pricing Adjustment.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 8.668 | 9.158 | 9.341 |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | | | | Project (Number/Name) 381A / <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 381A: <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i> | 20.780 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

The focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by combining bimolecular research with lifestyle change strategies to detect CVD at an early stage, and identifying markers of increased risk for heart attack in Service members.

No funding programmed. Beginning in FY19, the ICHP funding line is transferred from the Army to USUHS Project 381.

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

N/A

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

N/A

Remarks

N/A

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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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 382A / <i>CoE-Pain Center of Excellence (Army)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 382A: <i>CoE-Pain Center of Excellence (Army)</i> | 6.436 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Pain Center of Excellence (Army) | 0.000 | - | - |
| Description: The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

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

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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 382B: CoE-Pain Center of Excellence (USUHS) | 10.901 | 3.202 | 3.376 | 1.945 | - | 1.945 | 2.014 | 2.084 | 2.156 | 2.229 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <p>Title: Pain Center of Excellence (USUHS)</p> <p>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.</p> <p>FY19 Accomplishments: Obtained approval for the DVCIPM Pain BioBank. The Pain Registry Biobank is a clinical data registry and tissue biobank for the advancement of pain-related research. This Biobank contains PASTOR survey data, the Defense and Veterans Pain Rating Scale (DVPRS), electronic health record data, and biospecimens, (blood and saliva) on targeted individuals eligible for care within the Military Health System. Specimens are being processed in collaboration with the Center for Neuroscience and Regenerative Medicine (CNRM) laboratory.</p> <p>In addition to the DVCIPM site at Madigan Army Medical Center, additional study sites were established at Naval Medical Center San Diego and Joint Base San Antonio. Staff at these locations are seeking approval for the Pain Biobank Registry project.</p> <p>Set up Cooperative Research and Development Agreement's (CRADA) with the University of Washington, Virginia Tech, University of New Mexico and facilitated the development and implementation of PASTOR, through a CRADA at West Virginia University Medical Center. Additionally, the Defense & Veterans Pain Rating Scale (DVPRS) has been integrated into clinical practice and research outside of the DoD. Examples include the Durham VA, and West Virginia University and American Society of Acupuncturists, who rebranded the DVPRS with their own logos.</p> | 3.202 | 3.376 | 1.945 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>Obtained several grants including a CDMRP Peer-Reviewed Medical Research Program grant targeting biomarkers of chronic pain maintenance and recovery, and one examining integration of massage therapy services into primary care.</p> <p>Obtained funding to execute and evaluate a pilot program, adapting the Joint Pain Education Program (JPEP) for online continuing medical education, across the National Capital Region.</p> <p>Developed and piloted a Opioid Overdose Education & Naloxone Distribution (OEND), which is now included, in part, in the Stepped Care Model training and is currently being planned for a scaled-up, enterprise-wide roll-out.</p> <p>Established a Memorandum of Agreement with the Defense Health Agency to collaborate on education, training, and research related to pain management and opioid risk reduction in the DoD. Established and maintained collaborations in DHA, providing on-going subject matter expertise and analytics. Facilitated the expansion of PASTOR to include new users and military treatment facilities and the roll-out of the Stepped Care Model for Pain. DVCIPM became a voting member on the DHA Pain Clinical Support Service.</p> <p>Published the Acute Pain Medicine Text Book which was written and edited under the auspices of Oxford Press and the American Academy of Pain Medicine’s Shared Interest Group. Acute Pain Medicine is the first comprehensive, case-based text of its kind that explores the essential topics of acute pain medicine, including interventional, pharmacologic, and diagnostic considerations</p> <p>FY 2020 Plans: The DVCIPM will continue to focus on further building and streamlining the Pain Assessment Screening Tool and Outcomes Registry (PASTOR) and apply for funding for data analysis. Continue to foster collaborative relationships and focus on complementary and integrative pain management (CIPM) through clinical assimilation studies of modalities such as: battlefield acupuncture (BFA); yoga and massage; evaluation of novel analgesics; and interventional technologies for improved pain management. DVCIPM will seek additional funding to sustain the Pain Education Program, as well as support the increasing requirements for the MHS DVCIPM’s designation as a MHS CoE, and DVCIPM’s recognized track record of effective facilitating collaborations across the Uniformed Services, VA, and Civilian Medicine has resulted in an ever-growing number of tasks.</p> <p>FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. Efforts will be scaled back as funds were adjusted to higher priority programs.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| As a result of internal decisions, \$10M of PE 0603115 (\$1.5M in Project Code 382B) was re-prioritized which reduced research funding in the areas of health services delivery improvement, pain management and alternatives to opioids, cardiac health, and the development of technologies supporting warfighter health and recovery. | | | |
| Accomplishments/Planned Programs Subtotals | 3.202 | 3.376 | 1.945 |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 383A: <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i> | 49.072 | 7.921 | 8.359 | 8.526 | - | 8.526 | 8.696 | 8.870 | 9.047 | 9.228 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | | | |
|---|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: CoE-Prostate Cancer Center of Excellence (USUHS) | 7.921 | 8.359 | 8.526 |
| Description: The CPDR is at the forefront of “cutting-edge” clinical, basic science and epidemiologic research. The emphasis is on improving diagnosis, prognosis and treatment of prostate cancer involving new modalities such as MRI guided biopsy, gene-based biomarkers, and precision medicine strategies targeting causal gene alterations in prostate cancer. The CPDR multi-center database is a unique programmatic resource, enrolling over 27,500 DoD health care beneficiaries under suspicion for prostate cancer, with longitudinal follow up to 23 years. This database continues to highlight emerging issues in prostate cancer management such e.g., treatment outcomes, racial/ethnic differences, quality of life and discovery of novel molecular prognostic markers. In light of current issues related to overtreatment of early detected prostate cancers and poorly understood biology of prostate cancer, CPDR’s long-term biospecimen banks, high-impact discoveries and collaborations are leading towards better diagnostic and prognostic molecular markers and therapeutic targets with promise in improving the management of the disease. The CPDR’s health disparity research focus has uniquely benefited from studying a prostate cancer patient cohort, with a high representation of African American men, in an equal-access military health care system. Ground-breaking studies of the most validated prostate cancer gene, ERG, in over 1,500+ patients provide the first definitive information on prostate cancer biology underscoring racial/ethnic differences with potential to enhance personalized medicine. The CPDR’s state-of-the-art research infrastructure and framework is providing education and training for over 100 next generation physicians, scientists, medical and graduate students within DoD medical institutions. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>Accomplishments (FY19):</p> <ul style="list-style-type: none"> Renewed infrastructure (research laboratory and CAP-certified biospecimen bank) to enhance translational research within the equal access healthcare of the DoD Introduced new and continued successful immunotherapy clinical trials, such as, ProstAtak vaccine trial as adjuvant for localized disease and for intermediate risk prostate cancer and began autologous cellular immunotherapy for active surveillance patients Continued the TRUMPET clinical trial for castration-resistant prostate cancers which assesses the effectiveness of treatment sequencing. Evaluated Rucaparib therapy of metastatic castration-resistant prostate cancers with BRCA 1 / 2, ATM, or CHEK mutations Continued the Multi-disciplinary Prostate Cancer CoE/NCI clinics to determine treatment strategies based on cutting-edge clinical trials Evaluated the predisposing germline mutation BRCA1/2 for aggressive prostate cancer for improved therapeutic stratification to enhance therapy (Petrovics et al., PCPD 2018) Completed the assessment of new and more potent derivatives of the small molecule inhibitor ERGi-USU with potential impact on precision medicine/targeted therapy for ERG positive cancers (Mohamed, Xavier et al., Cancer Research 2018) Provided new insights into the tumor suppressor function of LSAMP gene, frequently deleted in prostate cancers of African American men (Babcock et al., AACR 2019) Continued focus on racial differences in prostate cancer to develop more precise urine-based biomarkers Assessed predictors of disease progression, including: intensity of PSA screening history, comorbidity, and race-treatment interactions Conducted multiple studies to improve clinical risk stratification and better tailored treatment by complementing pathologic patient features with molecular data <p>Knowledge Products (FY19 - 9 Publications); Podium Presentations (FY19 - 7 Presentations); Poster Presentations (FY19 – 11 Presentations)</p> <p>Materiel Products (FY19) U.S. Issued Patent No.: US 10,238,639 B2, date of patent: March 26, 2019. Azophenols as ERG Oncogene Inhibitors U.S. Published Patent Application No.: US 2018/0024132 A1, date: January 25, 2018. Lipid, Protein, and Metabolite Markers for the Diagnosis and Treatment of Prostate Cancer U.S. Provisional Applications No.: 62/867/029 filed on June 26, 2019: Markers for the Diagnosis of Prostate Cancer</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>No.: 62/779,035 filed on December 13, 2018: Genomic Rearrangements Associated with Prostate Cancer and Methods of Using the Same</p> <p>FY 2020 Plans: Precision Medicine Focus: Continue to leverage long term assets of DoD patient database (30K subjects with up to 25 yrs of follow up) and biospecimen bank (230K aliquots) towards delineation of molecular markers to enhance treatment decisions through precision medicine with emphasis on racially diverse patients in equal access military healthcare system. Define prostate cancer prevention strategies by addressing the role of predisposing conditions, military-specific exposures, and genetic components in prostate cancer onset and progression of service members. Validate prediction models for disease progression, quality of life, and overall survival across the spectrum of cancer treatments and determine factors that predict definitive treatment for patients initially managed on active surveillance. Develop modalities for diagnosing and prognosing clinically significant prostate cancers to reduce over diagnosis and treatment, through molecular/clinico-pathologic prognostic signatures of MRI-ultrasound fusion image guided biopsy specimens. Enhance pre/post-operative follow-up for cancer diagnosis, progression, pain, mobility deficits and restoration of function through the CoE's long-term database. Continue to strengthen the Cancer Moonshot and APOLLO prostate cancer proteogenomics discovery and targeted therapy focus under the Murtha Cancer Center aligned with the national cancer precision medicine initiatives. Validate prognostic biomarker panels developed from biofluid-based metabolome, proteome and lipidome analyses addressing the limitations of currently used serum PSA diagnostic test in multi-center validation setting.</p> <p>Health Disparity Research: Continue to lead discoveries of prostate cancer causing genes for diagnosing, prognosing and targeted therapy of racially diverse DoD prostate cancer patients with indolent and aggressive disease. Leverage established key collaborations with DoD academy and industry to integrate whole genome, whole-transcriptome sequencing, proteome, lipidome and metabolome analyses on a large CPDR cohort of African American and Caucasian American patients. Delineate the prostate cancer genomic landscape of under studied African American, Asian and Hispanic patients towards the development of broadly applicable diagnostic, prognostic markers and treatment approaches. Develop innovative experimental models for establishing the mechanisms of newly discovered race/ethnicity associated prostate cancer genes towards ethnicity-informed therapeutic strategies. Continue to leverage established collaborations with NCI investigators addressing race/ethnicity associated genetic predisposition for metastatic prostate cancer.</p> <p>Development of Molecular Diagnostic and Prognostic Tools:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>Strengthen the CoE's unique DoD prostate cancer research resources by employing advanced informatics and logistic platforms for enhancing the integration of clinical, biospecimen and molecular databases towards the development of diagnostic and prognostic tools.</p> <p>Validate in multi-center setting the prognostic utility of CoE developed prostate cancer biomarkers including urine exosome-based mRNA panels, serum multi-omics based panels, cytogenetic tests and the ERG monoclonal antibody (e.g., urine exosomes clinical trial in collaboration with the Exosome Diagnostics Inc.).</p> <p>Continue to enhance knowledge of prostate cancer driver genes as exemplified by CoE leadership in the discovery/delineation of biological function and biomarker/ therapeutic utility of the most common prostate cancer gene, ERG.</p> <p>Expand the research on serum and urine based protein and omics-defined biomarkers including serum antigen- autoantibody-based and mass spectrometry-based detections.</p> <p>Novel Strategies for Stratification and Treatment of Prostate Cancers:</p> <p>Continue to employ state-of-the-art clinical trials and research evaluating novel therapies for androgen axis inhibitors and immuno/ radiation therapy complemented by emerging approaches targeting newly discovered prostate cancer driver gene alterations (e.g., ERG and DNA repair gene defects).</p> <p>Evaluate strategies for enhancing immunotherapy of advanced prostate cancer.</p> <p>Complete developments of new small molecule ERG inhibitors in collaboration with Stanford Medical School to enter Phase I clinical trials.</p> <p>Develop innovative cell culture, engineered mouse models and tumorigenicity models for defining the mechanisms of prostate cancer driver genes with the objective of discovering new therapeutic opportunities.</p> <p>Leverage newly developed concepts of combination therapies targeting adaptive mechanisms of prostate cancer progression, e.g., androgen receptor (and its modulator, PMEPA1) in combination of TGF-beta inhibitors or NOTCH1 inhibitors in the context of early stage and advanced disease.</p> <p>Develop multi-center evaluation of the CPDR androgen receptor function index (ARFI) gene panel towards earlier and more effective stratification of patients for androgen axis targeting drugs.</p> <p>Education and Training Program:</p> <p>Leverage the strong track record in translational research training of the next generation of physicians, researchers, medical researchers at DoD institutions, e.g., WRNMMC urology residents, post-doctoral fellows, USU Capstone medical and graduate students.</p> <p>Enhance patient education focusing on quality-of-life, active surveillance and new treatment opportunities and integration with patient support groups.</p> <p>FY 2021 Plans:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 |
| FY 2021 plans continue efforts as outlined in FY 2020. | | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation. | | | | |
| Accomplishments/Planned Programs Subtotals | | 7.921 | 8.359 | 8.526 |
| 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 2021 Defense Health Agency **Date:** February 2020

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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) 398A / <i>CoE-Neuroscience Center of Excellence (USUHS)</i> |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 398A: <i>CoE-Neuroscience Center of Excellence (USUHS)</i> | 3.679 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - |

Note

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

The Military Clinical Neuroscience Center of Excellence (MCNCoE) is to improve prevention, diagnosis, and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions. The MCNCoE's approach to its goals includes supporting the research potential of military treatment facilities across the DOD system as well as the national capital area, and facilitating a network of collaborations between investigators across these facilities.

A. Mission Description and Budget Item Justification

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

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

N/A

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 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 429A / Hard Body Armor Testing (Army) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--------------------------------------|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 429A: Hard Body Armor Testing (Army) | 1.356 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - |

A. Mission Description and Budget Item Justification

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

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Hard Body Armor | 0.000 | - | - |
| Description: Develop a surface-mounted sensor system that will add critical dynamic data to the current clay test procedure and develops human skull fracture injury criteria for focused blunt impacts to the human head. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--------------------------------------|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 431A: Underbody Blast Testing (Army) | 48.611 | 10.800 | 9.200 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - |

A. Mission Description and Budget Item Justification

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

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Underbody Blast Testing | 10.800 | 9.200 | 0.000 |
| Description: Testing will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or IED, and the biomedical basis for the development of a Warrior-representative blast test manikin and associated biomedically-validated injury criteria that can be used to characterize dynamic events and injury risks for LFT&E crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats. | | | |
| FY 2020 Plans: Human Injury Probability Curves, Injury Assessment Reference Curves, and Female cadaver testing will be completed and the WIMAN research team will report on ways to account for female skeletal properties in the ATD. WIAMan Post-Mortem Human Subject data will be cataloged and stored at the Army Research Lab Engineering Analysis Branch (EAB) for Verification, Validation and Accreditation activities for Live Fire vehicle testing. Data sharing will be coordinated with medical research labs. | | | |
| FY 2021 Plans: Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 431A / <i>Underbody Blast Testing (Army)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 10.800 | 9.200 | 0.000 |

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

N/A

Remarks

D. Acquisition Strategy

Produce BRC and human injury probability curves for human skeletal response and tolerance in the military UBB environment and transition them to the Program Execution Office for Simulation, Training and Instrumentation for use in the development of the WIAMan UBB test manikin and for general use in the research, 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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 448A: <i>Military HIV Research Program (Army)</i> | 31.454 | 7.185 | 7.877 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | | | |
|--|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Military HIV Research Program | 7.185 | 7.877 | 0.000 |
| Description: The Military HIV Research Program aims to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. In addition, program also aims to develop other prevention and treatment strategies to mitigate the HIV epidemic globally. This project down-selects one or more vaccine candidates that are optimized through pre-clinical studies in non-human primates and conducts human clinical trials in Africa, Asia and the U.S. to test for safety and immunogenicity (ability to invoke an immune response), and early proof of concept efficacy testing. | | | |
| FY 2020 Plans: The Military HIV research program is conducting Early Capture HIV Cohort studies in Europe and Asia with the purpose of characterizing recruitment, retention, HIV prevalence, HIV incidence and biological characteristics of acute HIV infection in high risk volunteers. Human population studies in Asia, Europe and West Africa are being conducted to provide knowledge about the earliest HIV events to inform vaccine development. Human clinical trials in Africa, Asia and the U.S. designed to test for safety, immunogenicity and early proof of concept efficacy of candidate vaccines are ongoing. | | | |
| FY 2021 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 448A / <i>Military HIV Research Program (Army)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | | |
| Accomplishments/Planned Programs Subtotals | | 7.185 | 7.877 | 0.000 |
| C. Other Program Funding Summary (\$ in Millions) N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy Mature and demonstrate candidate HIV vaccines, prepare and conduct human clinical studies to assess safety and effectiveness of candidate HIV vaccines. All HIV technology development activities will be conducted in compliance with FDA regulations. Best selected candidates will be transitioned to advanced development through Milestone B. | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 830A / Deployed Warfighter Protection (Army) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 830A: <i>Deployed Warfighter Protection (Army)</i> | 34.106 | 5.713 | 6.345 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | | | |
|---|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Deployed Warfighter Protection | 5.713 | 6.345 | 0.000 |
| Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects. | | | |
| FY 2020 Plans: The Deployed Warfighter Protection research project continues to conduct translational research to develop and field tools that protect against emerging infectious disease threats and enable deployed forces to enhance protection from biting insects, primarily mosquitoes and sand flies, which transmit force degrading diseases. The AFPMB Vector Control Capabilities Gap Analysis (completed in FY 2016) will continue to be used to inform the development of functional and performance requirements for future acquisition programs. In addition, the AFPMB continues to develop the necessary test and evaluation plans to determine a candidate product's ability to meet its stated requirements. | | | |
| FY 2021 Plans: Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 5.713 | 6.345 | 0.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 830A / <i>Deployed Warfighter Protection (Army)</i> |

C. Other Program Funding Summary (\$ in Millions)
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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 478: <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i> | 14.766 | 14.237 | 18.556 | 18.640 | - | 18.640 | 18.724 | 19.098 | 19.480 | 19.870 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

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

| | | | |
|--|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: DoD Cancer Moonshot - Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS) | 14.237 | 18.556 | 18.640 |
| Description: Description: DoD's Cancer Moonshot at USU's MCC is a research program consisting of two overall projects, the first known as APOLLO (Applied Organizational Learning and Outcomes), and the second as DoD Framingham. | | | |
| APOLLO is a novel high-throughput molecular analysis of every DNA (gene), RNA, and protein expression molecule in cancer patient tumors. Such analysis has never been done on a large scale across multiple cancer types, and small pilot studies demonstrate that the APOLLO project will result in unprecedented findings across all types of cancer (with specific focus on cancers of the greatest threat to ASDMs). These new findings will be identified by using state-of-the-art tissue collection procedures in the operating rooms of all patients undergoing cancer surgery at MCC collection protocol sites (e.g.. Walter Reed NMMC;NMC Portsmouth; NMC San Diego; Womack AMC; Keesler AFB) and, then, sequencing the entire DNA genome and RNA sequence at USU, while analyzing the entire protein expression profile of these same cancers in MCC's Proteomics Laboratory, as well as other affiliated protein laboratories. The vast molecular data that will be derived from these analyses (in the terabyte | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>and petabyte range and beyond) will be linked to clinical patient data as well as treatment outcomes data. These combined data sets will be housed in National Cancer Institute (NCI) secure cloud-based servers with restricted access for analytics by teams of bioinformatics experts (i.e., from government, university, and corporate entities) across the United States working on this endeavor. This complete bio molecular (global) expression profiling of thousands of cancers of all types seen in military treatment and other facilities will predictably result in a myriad of new discoveries regarding the way cancers develop, progress, respond to treatment, evade treatment, and spread. It also will result in new ways to combat cancers and minimize side effects of cancer treatment, as well as identify novel cancer screening and prevention opportunities, while focusing on militarily-relevant cancers and ADSMs with cancer, distinguishing it from any effort that might develop in the future in a civilian organization, as none of this scale exists today. There are five specific APOLLO sub-projects, which are classified based on the organ type of cancer under study: APOLLO 1 = Lung cancer; APOLLO 2 = Gynecological cancer; APOLLO 3 = Prostate cancer; APOLLO 4 = Breast cancer; and APOLLO 5 = all other cancer types.</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 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>FY19 Accomplishments:</p> <ul style="list-style-type: none"> - Through APOLLO 1, 2, 3, and 4 ran nearly 1,000 total cancer specimens through the DNA, RNA, and protein molecular platforms per plan. - Final data analytics completed on APOLLO 1 (lung cancer) molecular platforms, and novel findings identified. Presented at various national scientific forums including MHSRS 2019. Publications in process. - Successfully opened all of our tissue source sites and biobank for APOLLO 5 in FY19, including a total of nine military treatment facilities across DHA. - Successfully began accruing APOLLO 5 prospective samples from one of our sites, and achieved IRB approval of APOLLO 5 at two additional sites (WR Bethesda and NMCS D). <p>FY 2020 Plans: Identify serum specimens and run them through the serum protein analysis lab platform, and perform initial data analytics on the results.</p> <p>FY 2021 Plans:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 |
| FY 2021 Plans continue efforts as outlined in FY 2020 | | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation. | | | | |
| Accomplishments/Planned Programs Subtotals | | 14.237 | 18.556 | 18.640 |
| 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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 479: Framingham Longitudinal Study (USUHS) | 4.920 | 4.746 | 4.920 | 4.920 | - | 4.920 | 4.920 | 5.018 | 5.118 | 5.220 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

DoD Cancer Moonshot Program - DoD Framingham

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

FY19 Accomplishments:

- Completed all mass spectrometry proteomic analysis of Framingham 1 specimens (approximately 900)
- Analyzed Framingham 1 data, identified important novel scientific findings, and presented these findings at four national and international meetings in FY19 including MHSRS 2019.
- Working on Framingham 1 publication manuscript
- Identified Framingham 2 and 3 serum specimens and began process of mass spectrometry workflow
- Identified Framingham 4 organ site (pancreatic cancer) and began scientific protocol development with combined DoD / NCI team

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: DoD Cancer Moonshot Program - DoD Framingham Longitudinal Study | 4.746 | 4.920 | 4.920 |
| Description: DoD Framingham is a novel project that is enabled by the blood serum specimens stored at the DoD Serum Repository at the Armed Forces Health Surveillance Branch (AFHSB) in Silver Spring, Maryland. This facility stores blood serum drawn from over 10 million ASDMs who were required to undergo mandatory semiannual blood testing for the last 25 years, resulting in this repository with over 65 million blood serum specimens. MCC tumor registry data, which includes every ADSM who developed cancer while on active duty, is matched to data in the Serum Repository. This allows MCC to identify the blood serum of ASDMs who ultimately develop cancer at key times, i.e., before they had cancer, during their cancer treatment, and | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 479 / Framingham Longitudinal Study (USUHS) |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>after their successful cancer treatment. Four different serum specimens (two before, one during, and one after cancer diagnosis and treatment) from every ADMS 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 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 ADMS 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 ADMS 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 2020 Plans: Continue to identify Framingham serum specimens and conduct serum protein analysis lab platform, and perform initial data analytics on the results.</p> <p>FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Funding remains the same.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 4.746 | 4.920 | 4.920 |

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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 2021 Defense Health Agency **Date:** February 2020

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|--|--|--|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 499: MHS Financial System Acquisition (DHA) | 15.222 | 20.358 | 15.373 | 1.971 | - | 1.971 | 6.011 | 6.051 | 6.092 | 6.143 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: MHS Financial System Acquisition | 20.358 | 15.373 | 1.971 |
| Description: The goal is to transition financial operations to a platform that allows for consistency across the Defense Health Agency, enabling standardized processes, data collection, and reporting. | | | |
| FY 2020 Plans: Additional research funding necessary to continue the consolidation all DHP appropriations into a single Financial Management System (FMS) system to provide the following capabilities: | | | |
| 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 2020 to FY 2021 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 | 20.358 | 15.373 | 1.971 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|---|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • BA 3: <i>PE 0807721</i> <i>Replacement & Modernization</i> | 10.409 | 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 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|--|---|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 381 / CoE - Integrative Cardiac Health Care (USUHS) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 381: CoE - Integrative Cardiac Health Care (USUHS) | 0.000 | 2.811 | 3.118 | 1.680 | - | 1.680 | 1.744 | 1.809 | 1.875 | 1.943 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

The USU Integrative Cardiac Health Program is a Center of Excellence whose mission is to:

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

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Integrative Cardiac Health Center of Excellence | 2.811 | 3.118 | 1.680 |
| 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 2020 Plans: The Integrative Cardiac Health Center of Excellence (ICHP) will continue development and refinement of clinical decision support tools and new models for cardiovascular and overall health; will conduct research studies to improve the health of the Active Duty force by investigating the effectiveness of personalized (gender specific) interventions specifically designed for the military and the effects of these interventions on preclinical atherosclerosis (plaque in arteries). Precision medicine efforts exploring novel biomolecular markers and tests as indicators for early (preclinical) cardiovascular disease risk assessment will continue. Will characterize new clinical phenotypes; detect cardiovascular disease in early stages when it is more likely to be reversible. ICHP will collaborate with Walter Reed Bethesda Cardiovascular Service, the Mayo Clinic, Abbott Laboratories, and Integrative Systems Biology for these efforts. ICHP will use this information to tailor personalized health interventions and build resiliency in the military population before disease affects quality of life. The Wounded Warriors project will continue to examine cardiovascular risk in the amputee and injured Warfighter and begin analysis of bio-samples collected to detect novel biomolecular markers. Study is designed to significantly advance the precision of risk detection and lead to an improvement of current interventions and patient outcomes. | | | |
| FY 2021 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 381 / <i>CoE - Integrative Cardiac Health Care (USUHS)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| FY 2021 Plans continue efforts as outlined in FY 2020. Efforts will be scaled back as funds were adjusted to higher priority programs. | | | |
| <i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> As a result of internal decisions, \$10M of PE 0603115 (\$1.5M in Project Code 381) was re-prioritized which reduced research funding in the areas of health services delivery improvement, pain management and alternatives to opioids, cardiac health, and the development of technologies supporting warfighter health and recovery. | | | |
| Accomplishments/Planned Programs Subtotals | 2.811 | 3.118 | 1.680 |

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

N/A

Remarks

D. Acquisition Strategy

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 504 / WRAIR Vaccine Production Facility Research (Army) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 504: WRAIR Vaccine Production Facility Research (Army) | 0.000 | 8.000 | 8.152 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

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

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

| | | | |
|---|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: WRAIR Vaccine Production Facility | 8.000 | 8.152 | 0.000 |
| Description: The WRAIR Vaccine Pilot Bioproduction Facility (PBF) will focus on the manufacture of early phase clinical materials for vaccine production from varied platforms, such as live virus, conjugates, recombinant proteins, DNA, and monoclonal antibody approaches that: (a) expand collaborative partnerships for product development that meet DoD requirements; (b) open active intramural-based discovery efforts of new products for development; and (c) initiate and extend strategic partnerships with external collaborators (Government and industry) to develop/co-develop potential new biologic approaches to pandemic disease preparedness. | | | |
| FY 2020 Plans: The WRAIR PBF program will continue vaccine and biologic production efforts for use in early phase clinical trials to assess safety and effectiveness of candidate vaccines. | | | |
| FY 2021 Plans: Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 8.000 | 8.152 | 0.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 506 / Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 506: Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS) | 0.000 | 0.000 | 11.904 | 11.141 | - | 11.141 | 11.385 | 11.631 | 11.883 | 12.141 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <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 Theater Campaign Plan objectives to further research. The GHE research needs of the warfighter are expressed by the regular demand signal of the Joint Force through the Joint Staff Surgeon’s Office and the Combatant Commands Surgeons’ Offices.</p> <p>Precision Medicine will provide standardized genome profiling services across the MHS. It will provide genomic data analysis and storage under DoD security and privacy compliance policies in order to provide cutting edge genomic information to clinicians and improve health care of warfighter.</p> <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> | 0.000 | 11.904 | 11.141 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <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 2020 Plans: Health Services Research: - Define research priorities: Health economics, geographic variation, provider induced demand, disparities, improving care to populations of patients, outcome studies, program evaluation. - Improve policy and practice in the MHS through knowledge translation.</p> <p>Global Health Engagement: - Improve the efficacy of military medical engagements with partner nations in achieving military outcomes - Improve the readiness of the Joint Force to conduct GHE activities in support of Geographic Combatant Commands and national security objectives - Improve the quality of tools and capabilities available to commanders for conducting international security cooperation and cooperative health security engagements</p> <p>Precision Medicine: - Enable single collection site of genomic data for DoD Precision Medicine studies to contribute towards population medicine innovation. - Improve utility for supercomputing infrastructure supporting clinical activities.</p> <p>Women's Health research: - Support research projects in the areas of reproductive health, pain, mental health, cardiovascular disease, cancer, human performance and readiness standards, nutrient and energy requirements for servicewomen, medical simulation violence against women, opioid use and, clinical practice guidelines.</p> <p>Infectious Disease Research: - Execute multisite research through a robust sustainable MHS research network, with capability to execute FDA-regulated clinical trials.</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>- Translate generated high quality evidence as follows: Develop new and refined DoD clinical practice guidance in support of Force Health Protection, inform DoD and National policies related to the prevention and management of infectious diseases, and provide direct support of infection threat assessment and mitigation efforts to the Geographic Combatant Commands in collaboration with Military Public Health authorities.</p> <p><i>FY 2021 Plans:</i> FY 2021 Plans continue efforts as outlined in FY 2020. Efforts will be scaled back as funds were adjusted to higher priority programs.</p> <p><i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> As a result of internal decisions, \$10M of PE 0603115 (\$1.0M in Project Code 506) was re-prioritized which reduced research funding in the areas of health services delivery improvement, pain management and alternatives to opioids, cardiac health, and the development of technologies supporting warfighter health and recovery.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 11.904 | 11.141 |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 507: Brain Injury and Disease Prevention, Treatment and Research (USUHS) | 0.000 | 0.000 | 13.317 | 13.583 | - | 13.583 | 13.855 | 14.132 | 14.415 | 14.703 | 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: Brain Injury and Disease Prevention, Treatment and Research | 0.000 | 13.317 | 13.583 |
| <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.</p> <p>FY 2020 Plans: The USUHS plans for FY 2020 are to:</p> <ul style="list-style-type: none"> - Screen for drug candidates that interfere with brain tau prion formation, a defining feature of CTE and other neurodegenerative diseases and maximize their bioavailability and therapeutic effectiveness. - Identify compounds that will enter the brain and bind with aggregated tau prions and can be used as PET tracers for diagnosis and markers of disease progression. - Develop animal models of tau prion formation to test efficacy of putative drug candidates - Using candidate drugs identified under this program, prepare to initiate clinical trials in at-risk service members for the treatment or prevention of CTE and other tau prion-related disorders. <p>FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 |
| Annual price adjustment. | | | | |
| Accomplishments/Planned Programs Subtotals | | 0.000 | 13.317 | 13.583 |
| 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 2021 Defense Health Agency **Date:** February 2020

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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 508: Psychological Health and Resilience (USUHS) | 0.000 | 0.000 | 7.000 | 7.140 | - | 7.140 | 7.283 | 7.428 | 7.577 | 7.729 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Psychological Health and Resilience | 0.000 | 7.000 | 7.140 |
| 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 2020 Plans: - Maintaining the current data and biospecimens for future analyses -- Historical Administrative Data Study (HADS), survey data, and biorepository. - Conduct future wave of data collection from original STARRS-LS Army sample and link to historical data records. - Develop prediction algorithms for suicide attempts and other outcomes. - Provide the resultant knowledge to the Army and DoD for use in modifying recruitment algorithms and developing targeted early preventive intervention programs for Soldiers at high risk of adverse outcomes. | | | |
| FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 7.000 | 7.140 |

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

N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 509: <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i> | 0.000 | 0.000 | 19.323 | 13.710 | - | 13.710 | 14.104 | 14.505 | 14.916 | 15.334 | 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness | 0.000 | 19.323 | 13.710 |
| Description: The TTW program aims to support highly collaborative advanced technology projects by bringing together industry, academia and civilian medical centers including minority serving institutions with experience in solving defense and civilian health problems. Supported projects will focus on the 3 principal medical areas for defense health (Combat Casualty Care, Military Operational Medicine, and Clinical and Rehabilitative Medicine) with an emphasis on direct relevance to identified military needs, translational potential and clear strategy for product commercialization with a low to medium risk – high reward payoff. Additionally, for USU, the TTW program will cultivate, establish and leverage partnerships between USU faculty/investigators and industry, academia and civilian medical centers including minority serving institutions. Results from the TTW program will increase DoD’s workforce capability, DoD’s access to leading edge technologies and leverage industry knowledge and funded research data for warfighter medical needs. | | | |
| Surgical Critical Care (SC2i) will enroll critically ill patients, leveraging deep medical and –omics data to develop Clinical Decision Support Tools (CDSTs) that will improve clinical outcomes and lower resource utilization across military and civilian healthcare systems. The CDSTs will further assist readiness by either accelerating return to duty (abridged length-of-stay across the ICU, general ward, and rehabilitation continuum of care) and curbing medical resource burdens. | | | |
| Rehabilitation Sciences Research supports clinical and translational research efforts dedicated to enhancing the rehabilitative care of the wounded warrior, particularly those with 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 | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>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.</p> <p>FY 2020 Plans: Transforming Technology for the Warfighter: - Support the advancement of medical technologies such as 1) wearable devices (e.g. enhanced performance monitoring using biosensors), 2) operational injuries (e.g. TBI, blast injuries, trauma care), 3) rehabilitation (e.g. regenerative medicine, wound healing), 4) precision medicine (e.g. omics, biomarkers), and 5) rapid treatment and diagnostics at point of injury. - Cultivate, establish and leverage partnerships with industry, academia and civilian medical centers including minority serving institutions to create, innovate and advance disruptive medical technologies to address warfighter medical needs.</p> <p>Surgical Critical Care: - SC2i will leverage a databank to develop, validate, and/or deploy eleven (11) predictive algorithms for conditions associated with high mortality and morbidity (e.g. timing of closure of extremity and open abdominal injuries, venous thromboembolism, pneumonia, bacteremia, acute kidney injury, acute respiratory distress syndrome, heterotopic ossification, small bowel obstruction, acute appendicitis, and vasospasm for severe traumatic brain injuries). - It will support robust medical education and training to ensure the battlefield surgeons of tomorrow are appropriately trained in the use of clinical and biomarker-based CDSTs.</p> <p>Rehabilitation Sciences Research: - Define the optimal rehabilitation strategies and prosthetic selection, fitting and training for wounded warriors with osseointegration (direct skeletal attachment of a prosthesis) - Examine the clinical efficacy of virtual and augmented reality applications to enhance rehabilitation of individuals with extremity dysfunction and acquired brain injury. - Develop clinical applicable tools to objectively assess gait for individuals with lower limb amputation and dysfunction - Explore potential rehabilitative interventions to mitigate heterotopic ossification formation from blast thru translatable model - Understand the bio-psycho-social and genetic factors that influence symptomatology and response to novel treatments for individuals with TBI, Amputation, and PTSD, including phantom limb pain, secondary back pain, and post-concussive symptoms.</p> <p>FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. The Technology Research Program efforts will be scaled back as funds were adjusted to higher priority programs.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| As a result of internal decisions, \$10M of PE 0603115 (\$6.0M in Project Code 509) was re-prioritized which reduced research funding in the areas of health services delivery improvement, pain management and alternatives to opioids, cardiac health, and the development of technologies supporting warfighter health and recovery. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 19.323 | 13.710 |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 373: GDF - Medical Technology Development | 1,006.232 | 123.885 | 78.868 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development 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 2019 | FY 2020 | FY 2021 |
| 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. | 123.885 | 78.868 | 0.000 |
| FY 2020 Plans: Medical simulation and information sciences technology maturation progressing to focus on developing and integrating pharmacodynamics (effects of drugs and the mechanism of their action) and pharmacokinetics (movement of drugs within the body) algorithms into an open source physiology research engine used to support a repository that contains simulated pharmaceuticals and other resuscitative treatments that are the most relevant to point of injury and en-route care training. It will incorporate the side effects of the drugs and drug on drug interactions to elicit how to deal with additional acute reactions. This repository is designed to improve medical simulation and training. Research will also continue to focus on assessment system tools with emphasis on combat casualty care training. Continuing efforts to optimize synthetic materials used in part-task mannequins, full body mannequins, or peripherals that could be used on the Advanced Modular Manikin in order to better represent tissues under different environments. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <p>Military infectious diseases progressing research supporting the inter-service efforts between DoD clinical and research and development groups to develop novel and innovative therapeutics and delivery technologies for combat wound infections. Ongoing multi-year studies addressing critical research focus areas in wound infections, such as improved treatment options for infections with multi-drug resistant organisms, to be supported. These efforts will be in alignment with the National Action Plan for Combating Antibiotic-Resistant Bacteria. Results of studies to develop antibacterial agents and clinical practice guidelines for better wound infection management to be evaluated for down-selection. Efforts continuing aimed at partnering with other entities to rapidly accelerate promising, innovative drug and vaccine solutions to combat emerging infectious diseases (e.g., Chikungunya, MERS, Zika).</p> <p>Military operational medicine: Researchers will continue to collect blast exposure data to validate whole body models of blast injury exposure in the training environment. Research progresses to refine and improve predictive auditory injury models in order to update acoustic injury standards for health hazard assessment. Efforts to develop tools to optimize return to duty after lower extremity (foot and ankle) injury, and head supported mass acute injury predictive models for mounted and dismounted environments are ongoing. Progressing data collecting to improve multisensory cueing criteria for aircrew performance optimization in degraded visual environments. Research focuses to evaluate longitudinal data collected for dietary supplement use with correlation to usage patterns with associated negative and positive health effects. Research focuses to provide guidance on the effects of healthy cooking for food choice behaviors, nutritional status, and psychological states in Wounded Warriors and their families. Also, studies continue evaluating the physical demands associated with selection to historically male military occupations to develop gender-neutral Military Occupational Specialty assignment standards. Ongoing research aimed at delivering assessment, prevention, and treatment interventions and tools that mitigate substance abuse, including prescription drug misuse and alcohol and other drug abuse. Efforts toward delivery of interventions to prevent suicide behaviors and conduct clinical trials to test the efficacy of the interventions are progressing. Studies aimed at delivering resilience building/prevention programs focused on education, skills, and novel service delivery methods for Service member and Family resilience are ongoing. Newly developed and existing large-scale PTSD datasets and state-of-the-art analytic methods are being used to produce individualized treatment guidelines for PTSD as well as PTSD-related sleep disturbances. Candidate biomarkers validation of exposure to inhaled or ingested toxic substances and develop medical guidance for risk assessment of adverse health outcomes are ongoing. Research continues its focus to provide validated metrics for optimized operational task performance in extreme environments. Efforts to validate novel methods for estimating thermal strain from non-invasive measures are progressing.</p> <p>Combat casualty care hemorrhage research will continue to evaluate immune system modulating drugs to treat hemorrhagic shock with a focus on the time period 4 to 72 hours post injury (relevant to prolonged field care). In addition, progressing work on the pathophysiological (functional changes associated with injury) impacts of using advanced hemorrhage (bleeding) control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Animal studies are ongoing to evaluate oxygen delivery solutions infused to maintain survivability for potential use in severe casualties where blood transfusion</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <p>is not available. Neurotrauma research will continue to focus on the development of novel technologies to better assess, monitor and maintain the stability of more severely injured TBI casualties closer to point of injury and during prolonged field care. Precision medicine research to improve the characterization of TBI, develop targeted therapies, devices, clinical guidelines, the impact of pre-injury conditions and the environment to improve the care provided to TBI casualties continues. Furthermore, neurotrauma research to investigate the impact of pre-injury conditions and the environment on Service member response to treatment and recovery following TBI. The program is leveraging data from Combat Operations to improve management of TBI by correlating injury events and medical records. Treatments for extremity trauma to develop specialized fracture stabilization techniques, address treatments for organ support and stabilization of craniomaxillofacial wounds will proceed to mature. Pre-hospital Tactical Combat Casualty Care will develop enhanced surgical procedures and equipment. En Route Care research will progress the development of specifications for an integrated system to support safe patient care and hand-offs, and the development of expanded en route care interventions and treatment capabilities. The military medical photonics program continues to develop light-based technologies and systems for combat casualty care, to include applications to detect blood pooling in the abdomen and oxygen content in the pulmonary artery. Photochemical cross-linking (the use of light to create new molecular bonds) to strengthen veins for grafting to arteries and the post-surgical benefits of photochemical bonding (the use of light to create new molecular bonds) in reducing scarring and adhesions are being studied. Research is being conducted on miniaturized sensors and actuators which can be inserted or implanted for important new kinds of diagnostic and therapeutic benefit.</p> <p>Radiation health effects research will continue to evaluate therapeutic candidates and radioprotectants for acute radiation exposure, and develop data to support preparation of a technical data package for investigational new drug applications. Research will develop data to support qualification of models for use in FDA approved trials. Objectives will include demonstrating improved survivability following high doses of radiation exposure with treatment at 24 hours and less after exposure.</p> <p>Clinical and rehabilitative medicine will conduct early human trials of promising products, evaluate preclinical safety of promising treatments, and test FDA-licensed products in the areas of neuromusculoskeletal injury, pain management, and regenerative medicine. Will support clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation outcomes after Service-related injuries. Will assess chronic pain risk factors and evaluate novel therapeutics and devices for pain management. Will assess preclinical and early clinical safety and efficacy of technologies designed to alter or regulate immune functions, skin substitutes to treat burn injury, treatments for volumetric muscle loss, treatments for segmental bone defects, and strategies for stabilization or regeneration of neuromuscular junctions for nerve injury.</p> <p>FY 2021 Plans: Efforts realigned to PE 0603115DHA Project Codes 373A-G.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Efforts realigned to PE 06031115DHA Project Codes 373A-G. | | | |
| Accomplishments/Planned Programs Subtotals | 123.885 | 78.868 | 0.000 |

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

N/A

Remarks

D. Acquisition Strategy

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 373A: GDF - MTD (Combat Casualty Care) | - | 0.000 | 0.000 | 11.168 | - | 11.168 | 15.736 | 16.756 | 19.649 | 20.114 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Joint Battlefield Healthcare (Formerly Combat Casualty Care) | 0.000 | - | 11.168 |
| 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 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | 11.168 |

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 2021 Defense Health Agency **Date:** February 2020

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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 373B: GDF - MTD (Military Operational Medicine) | - | 0.000 | 0.000 | 23.255 | - | 23.255 | 19.046 | 19.116 | 18.151 | 18.557 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Military Health and Recovery (Formerly Military Operational Medicine) | 0.000 | - | 23.255 |
| 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 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | 23.255 |

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

N/A

Remarks

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

D. Acquisition Strategy
N/A

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 373C: GDF - MTD (Medical Simulation & Training/Health Informatics) | - | 0.000 | 0.000 | 12.613 | - | 12.613 | 13.044 | 13.339 | 13.637 | 13.942 | 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: Medical Simulation Technologies (Formerly Medical Simulation Technologies & Training/Health Informatics) | 0.000 | - | 12.613 |
| Description: Studies, investigations, and non-system specific technology effort focus on prototyping tissue models, technologies that simulate medical condition progress over time, technologies that simulate injury, technologies that replicate warfighter bio-physiology, and, technologies that simulate high-fidelity combat casualty care scenarios. Activities will continue to focus on tissue models that accurately simulate the feel, pliability, flexibility, and responsiveness of live tissue; technologies that simulate the degradation or worsening of a medical condition over time, as well as simulate the improvement of a medical condition over time; technologies that simulate injury, especially hemorrhage, fractures, and ocular damage; technologies that accurately reflect warfighter bodily characteristics and are rugged enough to simulate patient care and movement throughout the entire continuum of care; technologies that simulate combat scenarios to provide realistic environments; and, technologies that simulate patient movement through the continuum of care. | | | |
| FY 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; | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 |
| technologies that simulate combat scenarios to provide realistic environments; and, technologies that simulate patient movement through the continuum of care. | | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | | |
| Accomplishments/Planned Programs Subtotals | | 0.000 | - | 12.613 |
| C. Other Program Funding Summary (\$ in Millions) | | | | |
| N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy | | | | |
| N/A | | | | |

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|--|--|---|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 373D: GDF - MTD (Clinical and Rehabilitation Medicine) | - | 0.000 | 0.000 | 13.040 | - | 13.040 | 14.980 | 15.034 | 14.275 | 14.595 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Clinical and Rehabilitation Medicine | - | - | 13.040 |
| 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 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 13.040 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 373E / GDF - MTD (Military Infectious Disease) | | | |
|--|-------------|---------|---------|--------------|--|---------------|---------|---------|--|---------|------------------|------------|
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 373E: GDF - MTD (Military Infectious Disease) | - | 0.000 | 0.000 | 6.409 | - | 6.409 | 6.630 | 6.779 | 6.932 | 7.087 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Military Infectious Disease | - | - | 6.409 |
| 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). | | | |
| 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). | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 6.409 |

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 2021 Defense Health Agency **Date:** February 2020

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|--|--|--|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 373F / GDF - MTD (Radiological Health Effects) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 373F: GDF - MTD (Radiological Health Effects) | - | 0.000 | 0.000 | 0.501 | - | 0.501 | 0.518 | 0.531 | 0.542 | 0.554 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Radiological Health Effects | - | - | 0.501 |
| 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 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 0.501 |

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 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 373G / GDF - MTD (Military Medical Photonics) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 373G: GDF - MTD (Military Medical Photonics) | - | 0.000 | 0.000 | 10.000 | - | 10.000 | 10.200 | 10.404 | 10.612 | 10.824 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Military Medical Photonics | - | - | 10.000 |
| 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 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 10.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |
| C. Other Program Funding Summary (\$ in Millions) N/A | | |
| Remarks | | |
| D. Acquisition Strategy N/A | | |