Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency											Date: May 2017	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0602115DHA *I Applied Biomedical Technology*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	245.770	64.974	57.275	63.550	-	63.550	73.654	82.883	84.408	86.096	Continuing	Continuing
200A: *Congressional Special Interests*	96.186	11.071	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
246A: *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	0.000	2.913	2.860	2.142	-	2.142	1.857	1.949	1.989	2.029	Continuing	Continuing
306B: *Advanced Diagnostics & Therapeutics Research & Development (AF)*	9.620	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
306C: *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	0.000	1.728	1.757	1.987	-	1.987	2.025	2.066	2.107	2.149	Continuing	Continuing
306D: *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	0.000	1.728	1.758	1.988	-	1.988	2.026	2.066	2.108	2.150	Continuing	Continuing
372A: *GDF Applied Biomedical Technology*	125.005	40.072	43.462	49.639	-	49.639	58.724	67.148	68.357	69.724	Continuing	Continuing
447A: *Military HIV Research Program (Army)*	14.959	7.462	7.438	7.794	-	7.794	9.022	9.654	9.847	10.044	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Applied Biomedical Technology: This program element (PE) provides applied research funding to refine concepts and ideas into potential solutions for military health and performance problems, with a view toward evaluating technical feasibility. 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 DoD Department of Defense and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of

state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research & Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, radiation health effects, and clinical and rehabilitative medicine. Funds in the PE support studies and investigations leading to candidate solutions that may involve use of animal models for testing in preparation for initial human testing. As research efforts mature, the most promising efforts will transition to technology development (PE 0603115) funding.

For the Army Medical Command, this PE funds the military HIV research program to refine identification methods for determining genetic diversity of the virus, to conduct preclinical work in laboratory animals including non-human primates to identify candidates for global HIV-1 vaccine, and to evaluate and prepare overseas sites for clinical trials with these vaccine candidates.

For the Army Medical Command, funding is provided to develop strategies to prevent, mitigate, and treat antibiotic resistant bacteria in wounds through the Combating Antibiotic Resistant Bacteria - WRAIR Discovery and Wound Program.

In FY 2016, Congressional Special Interest funds were provided for Traumatic Brain Injury and Psychological Health (TBI/PH) and Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	58.251	57.275	63.550	-	63.550
Current President's Budget	64.974	57.275	63.550	-	63.550
Total Adjustments	6.723	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	11.071	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-4.348	-			

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

	FY 2016	FY 2017
Project: 200A: *Congressional Special Interests*		

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0602115DHA *I Applied Biomedical Technology*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Congressional Add: *426A – CSI - Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)*	0.000	-
Congressional Add: *462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)*	10.000	-
Congressional Add: *469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army)*	1.071	-
Congressional Add: *469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force)*	0.000	-
Congressional Add Subtotals for Project: 200A	11.071	-
Congressional Add Totals for all Projects	11.071	-

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115-Applied Biomedical Technology (-$4.179 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$4.179 million).

FY 2015: Restore core research funding to the DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$25.303 million).

FY 2016: Restore core research funding to the DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$16.904 million).

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115-Applied Biomedical Technology (-$4.114 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$4.114 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0602115-Applied Biomedical Technology (-$8.797 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+$8.797 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0602115-Applied Biomedical Technology (-$3.350 million) to DHP RDT&E PE-0603115-Medical Technology Development for Breast, Gynecological and Prostate Cancer Centers of Excellence (+$3.350 million).

FY 2017: Rebalance Joint Program Committees by realigning from DHP RDTE PE 0605145-Medical Products and Support Systems Development (-0.625M) to DHP RDTE PE 0602115-Applied Biomedical Technology (+0.625M).

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0602115DHA *I Applied Biomedical Technology*

FY 2018: No changes.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*	Project (Number/Name) 200A / *Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
200A: *Congressional Special Interests*	96.186	11.071	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

The FY 2016 DHP Congressional Special Interest (CSI) funding was directed toward core research initiatives in PE 0602115 - Applied Biomedical Technology. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 426A – CSI - Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)	0.000	-
FY 2016 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) CSI program supported studies to inform the development of strategies to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on the function, wellness, and overall quality of life for military Service members and veterans, as well as their family members, caregivers, and communities. A key priority of the TBI/PH applied research program was to complement ongoing Department of Defense efforts to ensure the health and readiness of our military forces by promoting a better standard of care for psychological health disorders and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In support, the FY 2016 Military Operational Medicine Research Program Cognitive Resilience and Readiness Research Award Program Announcement was released to solicit research relevant to building and sustaining cognitive resilience in Service members and ensuring short- and long-term readiness of the force. A Broad Agency Announcement focused on supporting the implementation of evidence-based interventions identified by stakeholders for use within the military context as well as for system-wide dissemination. Additionally, studies to identify interventions for reducing the psychological impact of stress and sex differences in the ability to predict and treat opiate abuse were initiated.		
Congressional Add: 462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)	10.000	-
FY 2016 Accomplishments: This CSI initiative was directed toward FY 2016 DHP core research initiatives in PE 0602115. Funds supported applied research for military operational medicine, combat casualty care, and radiation health effects and clinical and rehabilitative medicine (Project 372A).		
Congressional Add: 469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army)	1.071	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 200A / *Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
FY 2016 Accomplishments: FY 2016 DHP CSI was directed toward core research initiatives in PE 0602115. Funds supported research in Military HIV Research (Project 447A) and Combating Antibiotic Resistant Bacteria (Project 246A).		
Congressional Add: 469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force) ***FY 2016 Accomplishments:*** No Funding Programmed.	0.000	-
Congressional Adds Subtotals	11.071	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Individual efforts are monitored through a quarterly project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives), key performance parameters, and resolution of Force Health Protection gaps. Variances, deviations, and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of Science and Technology governance. Annual reviews are also conducted in person for all of the projects within a specific program area.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 246A / *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
246A: *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	0.000	2.913	2.860	2.142	-	2.142	1.857	1.949	1.989	2.029	Continuing	Continuing

A. Mission Description and Budget Item Justification

At the President's direction in late 2013, a National Strategy was created to address the critical issue of antimicrobial resistance. This strategy was devised using an interagency approach and ultimately approved at the executive level (2014). Inherent in this work are DoD sponsored efforts to support the DoD's beneficiaries, but also complement national efforts to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria. One critical need identified is for new therapeutics, to include antibiotics. This effort's focus is on the development of new/novel antibiotics, especially those targeting the most resistant and worrisome Gram negative bacterial pathogens, using existing expertise at the Walter Reed Army Institute of Research (WRAIR), and leveraging other WRAIR capabilities to evaluate viable candidate targets for advanced discovery. This project supports (both directly and indirectly) Global Health Security Agenda priorities to respond rapidly and effectively to biological threats of international concern.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	2.913	2.860	2.142

Description: Focus on continued establishment of in-house capabilities for an antibacterial drug discovery program directed toward military relevant drug-resistant bacteria that a) encompasses assessment of external products/candidates/leads that may meet DoD requirements, b) opens active intramural based discovery efforts of new potential products/candidates/leads for development, and c) fosters partnerships with external collaborators to develop/co-develop new potential antibacterial treatment therapeutics.

FY 2016 Accomplishments:

Established collaborations with two universities and the National Center for Advancement of Translational Science (NCATS) at the National Institutes of Health, and additional industry collaborations were initiated. In conjunction with NCATS, WRAIR identified promising drug combinations to be further assessed. Robust internal screening efforts also yielded promising early lead candidates. Efforts focused on lead optimization by specific drug design and chemical synthesis, and novel compounds were identified in two known classes of antibiotics. New animal model and bacteria susceptibility panels were established using clinically relevant pathogens derived from military populations -- these are unique tools critical for the DoD antibacterial drug discovery effort.

FY 2017 Plans:

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 246A / *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Assess identified drug combinations in WRAIR animal models; if effective, the combinations could represent potential fast-track opportunities for clinical use. Continue to optimize lead candidates, synthesize newly designed, key chemical compounds for drug lead optimization, refine animal model standards, and pursue late stage external collaborations that could potentially treat military-relevant resistant bacteria. Establish partnership and intellectual property rights agreements where necessary to explore and co-develop new antibiotics leads. ***FY 2018 Plans:*** Plans to include establishing sustainable research efforts designed to evaluate viable small molecule candidate antibacterial agents for planned development for the DoD and Public Health benefit, continuing market analysis of external antibiotic programs, compound lead optimization, and Investigational New Drug-enabling study coordination, and establishing partnership and intellectual property rights agreements where necessary to explore and co-develop new antibiotics leads. In addition,screening against military relevant strains and biofilms (microorganisms in which cells stick to each other on a surface) to select compounds for continued development will be conducted. Specially, plans made to synthesize designed novel drugs for lead optimization efforts, exploit established in vivo (living organism) model standards, and to continue to evaluate late stage external programs that could potentially treat military relevant resistant bacteria.			
Accomplishments/Planned Programs Subtotals	2.913	2.860	2.142

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

An Acquisition Strategy will be developed to support future Milestone B when a clinical development candidate is identified and reaches Technology Readiness Level (TRL)-6.

E. Performance Metrics

Performance metrics of the CARB drug discovery program will be provided through semi-annual status reports, periodic reviews by the Military Infectious Diseases Research Program Integrating Integrated Product Team (IIPT) and in-process reviews (IPR). The performance metric benchmark is progression of research projects to TRL 5 and their schedule to transition.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*	Project (Number/Name) 306B / *Advanced Diagnostics & Therapeutics Research & Development (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
306B: *Advanced Diagnostics & Therapeutics Research & Development (AF)*	9.620	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

Advanced Diagnostics & Therapeutics Clinical Translational Applied Research (Air Force): This project provides applied research funding needed to increase efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Modernization Thrust Areas to improve and enhance clinical Diagnosis, Identification, Quantification and Mitigation (DIQM) methods, techniques protocols, guidelines and practices for all DoD wounded, ill and/or injured beneficiaries.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Advanced Diagnostics & Therapeutics Research & Development (AF) ***Description:*** This project provides applied research funding needed to perform research in the area of diagnostic assay development/refinement for diseases of operational significance. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and support research of evidence based therapeutics. ***FY 2016 Accomplishments:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed. ***FY 2018 Plans:*** No Funding Programmed.	0.000	0.000	0.000
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 306B / *Advanced Diagnostics & Therapeutics Research & Development (AF)*

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*	Project (Number/Name) 306C / *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
306C: *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	0.000	1.728	1.757	1.987	-	1.987	2.025	2.066	2.107	2.149	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project provides applied research funding needed to perform research in the area of assay development/refinement for diseases of operational significance/ conditions. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and research/development of evidence based therapeutics

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Adv Diagnostics & Epigenomics Applied Research (AF)	1.728	1.757	1.987

Description: This project provides applied research funding needed to perform research in the area of assay development/ refinement for diseases of operational significance/conditions. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and research/development of evidence based therapeutics.

FY 2016 Accomplishments:

In support of personalized treatment for type 2 diabetes (T2D) and cardiovascular disease, provide a predictive genetic therapeutic strategy based on pharmacogenetic therapies at the onset of diagnosis and aimed at delaying disease progression. Identify genetic markers for musculoskeletal injuries and ailments to implement preventive measures in military field training sites. Perform intramural project for the rapid identification of etiological pathogens of sepsis in support of same-day treatment-specific modalities. Leverage joint personalized medicine efforts to identify biomarkers of physiological response to opioid use. Transition smartphone-based pathogen identification system to meet Air Force requirements for personalized medicine and infectious disease characterization. Optimize molecular assays for polymerase chain reaction identification of Middle Eastern Respiratory Syndrome Coronavirus and Influenza AH7N9 to be implemented within the Center for Advanced Molecular Detection infectious disease surveillance operations. Analyze breath biomarkers as an accurate and non-invasive detection of influenza infection and as a method for prediction of the clinical course of disease. Develop Human Mesenchymal Stem Cells for Treatment of Immune System Dysregulation in Neurological Diseases. Identify biomarkers for mental illness recovery, producing a validated inpatient psychiatry psychometric and biological repository. Characterize novel early biomarkers for injury severity and the coordination of patient evacuation. Analyze genotypes phenotypes within NIH databases for Air Force precision medicine applications. Validate method of MRI measurement for volumetric quantification of traumatic brain injury. Examine genetic and epigenetic biomarkers for the prevention of cutaneous adverse drug reactions. Evaluate immune-modulators for pharmacological intervention on complement activation and coagulation. Analyze serotonin transporters and telomeres to produce an early method for PTSD risk

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 306C / *Core Adv Diagnostics & Epigenomics Applied Research (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
identification. Identify proximal drivers of inflammation to predict immune status and disease. Provide an analysis of the Chagas disease threat within high-risk military populations to determine if force health protection measures should be implemented to decrease exposure risk. Develop automated data analysis method for next generation sequencing to update AF influenza surveillance program, increase epidemiological surveillance scope and reduce per result costs. ***FY 2017 Plans:*** Continue to evaluate small, rapid, ruggedized molecular detection assays and technology. Develop and compare field-forward nucleic acid extraction/sample processing methods. Examine portable, multiplexed immunoassay arrays for multiple panels, to include toxins, viruses, bacteria and biomarkers on Personalized Bioinformatics. Expand pyrosequencing assays to include fungal pathogens to decrease the diagnostic time for determining the etiological agent of sepsis. Continue the development of pharmacogenomics-driven predictive risk profiles for improved management of complex diseases. Continue the evaluation of genetic, epigenetic and proteomic markers to improve preventive and diagnostic strategies. Continue to evaluate gene-environment interactions for tailored treatments based on individual, social, operational and environmental risk and protective factors, such as those associated with social-occupational impairment, resiliency, and psychological symptoms. ***FY 2018 Plans:*** Continue to evaluate small, rapid, ruggedized molecular detection assays and technology. Develop and compare field-forward nucleic acid extraction/sample processing methods. Examine portable, multiplexed immunoassay arrays for multiple panels, to include toxins, viruses, bacteria and biomarkers on Personalized Bioinformatics. Expand pyrosequencing assays to include fungal pathogens to decrease the diagnostic time for determining the etiological agent of sepsis. Continue the development of pharmacogenomics-driven predictive risk profiles for improved management of complex diseases. Continue the evaluation of genetic, epigenetic and proteomic markers to improve preventive and diagnostic strategies. Continue to evaluate gene-environment interactions for tailored treatments based on individual, social, operational and environmental risk and protective factors, such as those associated with social-occupational impairment, resiliency, and psychological symptoms.			
Accomplishments/Planned Programs Subtotals	1.728	1.757	1.987

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

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 306C / *Core Adv Diagnostics & Epigenomics Applied Research (AF)*

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 306D / *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
306D: *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	0.000	1.728	1.758	1.988	-	1.988	2.026	2.066	2.108	2.150	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project supplies applied research funding needed to further develop approaches aimed at increasing the understanding of AF occupational and environmental hazards, advancing new concepts in developing methods of treatment in aeromedical care, and exploring new mechanisms to enhance human performance in critical Air Force occupations in the defined Modernization Thrust Areas to improve and enhance, maintain, preserve, and restore personnel performance, with the end goal of positively affecting personalized health and performance.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)	1.728	1.758	1.988

Description: This project supplies applied research funding needed to further develop approaches aimed at increasing the understanding of AF occupational and environmental hazards, advancing new concepts in developing methods of treatment in aeromedical care, and exploring new mechanisms to enhance human performance in critical Air Force occupations in the defined Modernization Thrust Areas to improve and enhance, maintain, preserve, and restore personnel performance, with the end goal of positively affecting personalized health and performance.

FY 2016 Accomplishments:

Begin to develop advanced diagnostics for brain effects from hypobaria in USAF high altitude ops. Develop mitigation approaches and therapeutics to counter effects from air transport and low-dose hypobaric exposures to the brain and traumatized organ systems. Developed passive dosimeters to support 24/7 exposure monitoring. Expanded toxicological/functional testing of organ cell lines, development of new organ system cell lines and build library of multiple chemical exposure. Continued to develop environmental biosurveillance procedures for monitoring metagenomic drift within field hospitals and forward bases.

FY 2017 Plans:

Demonstrate through emerging advanced methods, brain injury from hyperoxemia/oxidant stress experienced in aircrew operations. Initial development of platforms linking biological characteristics to effects from individual and multiple environmental hazards for Total Exposure Health Initiative. Explore capture of assorted biological signatures to characterize health and physiological status.

FY 2018 Plans:

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 306D / *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Increase development of platforms linking biological characteristics to effects from individual and multiple environmental hazards for Total Exposure Health Initiative. Explore capture of assorted biological signatures to characterize health and physiological status. Proposed expansion of Genomic Studies to include analysis of conditions with operational and clinical importance, based on an assessment of AFMS needs. Continue AFMS Personalized Medicine initiatives including demonstration projects for leadings practices, evaluation and capitalization of emergent science and technologies. Utilization of patient modeling algorithms to identify pharmacogenomic interventions that can improve patient health and reduce healthcare costs across the AFMS.			
Accomplishments/Planned Programs Subtotals	1.728	1.758	1.988

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

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

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*	Project (Number/Name) 372A / *GDF Applied Biomedical Technology*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
372A: *GDF Applied Biomedical Technology*	125.005	40.072	43.462	49.639	-	49.639	58.724	67.148	68.357	69.724	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Applied Biomedical Technology: Applied biomedical technology research will focus on refining concepts and ideas into potential solutions for military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development. Applied research is managed by the Joint Program Committees in the following areas: 1- Medical Simulation and Information Sciences applied research is developing informatics-based simulated military medical training. 2- Military Infectious Diseases applied research is developing protection and treatment products for military relevant infectious diseases. 3- Military Operational Medicine applied research goals are to develop medical countermeasures against operational stressors, prevent musculoskeletal, neurosensory, and psychological injuries during training and operations, and to maximize health, performance and fitness of Service members. 4- Combat Casualty Care applied research is focused on optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through en route and facility care. 5- Radiation Health Effects applied research supports tasks for the development of radiation medical countermeasures. 6- Clinical and Rehabilitative Medicine applied research is focused on efforts to reconstruct, rehabilitate, and provide care for injured Service members.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: GDF Applied Biomedical Technology	40.072	43.462	49.639
Description: Applied Biomedical Technology Research focuses on refining concepts and ideas into potential solutions to military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development.			
FY 2016 Accomplishments: Military infectious diseases research supported multi-year studies in bacterial diseases, and continued the development efforts of four antibacterial projects and two projects for the detection of microbial infections in wounds. Studies were aimed at development of novel therapeutics (drugs), biomarkers, and clinical practice guidelines to mitigate wound infection and biofilm processes. Molecule(s) showing efficacy in laboratory studies and initial animal studies, and/or biomarkers demonstrating accuracy in identifying pathogens were evaluated for further development. Continued efforts to maintain subject matter expertise in acute respiratory diseases. These studies aligned with the National Strategy for Combating Antibiotic Resistance. Military operational medicine research validated repeated low level blast injury animal models compared to occupational blast exposures. Developed computational models of the nonlinear middle ear function to establish hearing injury criteria. Developed improved clinical strategies to determine safe return to duty after severe musculoskeletal injury, and characterized the effects of hypoxia (oxygen deficiency) and fatigue on aircrew performance in rotary and fixed wing aircraft. Conducted applied research to develop strategies for building Service member and family resilience and to support successful reintegration following deployment.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Continued to establish associations between military service, deployment, risk and protective factors, and psychological and physiological health problems to inform development of policies and guidelines. Continued research toward investigation of risk and protective factors associated with PTSD, the neurobiological and behavioral impact of various PTSD interventions, and the initiation of pilot research associated with novel, theoretically-based treatments. Developed interventions for sustainable weight loss in military families. Continued the development of computational models that can predict bone and muscle health status. Performed studies of risk factors for heat injury susceptibility and developed a non-invasive tool for diagnosing pulmonary disease. Conducted studies for novel mitigation and treatment strategies and biomarker detection to optimize physiological performance and protect against multi-environmental injury. Refined biomarkers of environmental exposure to toxic substances inhaled or ingested that will be used for establishing the probability of adverse health risk outcomes. Conducted studies to define metrics for optimized performance in extreme environmental conditions. Combat casualty care hemorrhage research continued to search for new diagnostic tools and the development of treatments for abnormal hemorrhage following injury. Work focused primarily on inflammatory modulation and coagulopathy of trauma. Forward Surgical and Intensive Critical Care studied the effectiveness of acute lifesaving surgical interventions and how to improve survival for those in need of critical care on the battlefield and in acute stages of injury. Treatments for tissue injury related to burn, acute lung injury, and enhanced healing of complex injuries of the face, extremities, groin and pelvis were studied. Tissue injury research addressed wound stabilization in the prolonged field care scenario and continued to specifically address the need for a maxillofacial stabilization dressing. En Route Care research studied the physiologic response to transport in air, sea, and ground environments and the appropriate time(s) to transport patients following injury. Radiation health effects research continued strategies for protection, mitigation, and treatment of radiation-induced tissue injury due to high doses of radiation exposure. Conducted animal studies in mice and non-human primates to evaluate several compounds with potential to mitigate or prevent Acute Radiation Syndrome (ARS) resulting from lethal doses of radiation. Mitigators and therapeutics of ARS addressed bone marrow (hematopoietic) and gastrointestinal effects. Pulmonary effects of radiation exposure were examined. Based on research accomplishments, compounds were evaluated as potential candidates for transition toward advanced development. Additional efforts evaluated targets for safe and effective candidate medical countermeasures for the mitigation or treatment of radiation injury, and increasing understanding of the molecular mechanisms by which radiation injuries are initiated and cell cycling pathways triggered leading to multi-organ system dysfunction and death. Clinical and rehabilitative medicine research pursued down-selection of candidate products for transition to technology development in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and sensory (hearing, sight, and balance) system traumatic injury. Conducted applied research in Service-related neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment, and rehabilitation. Studied the effectiveness of leading solutions to alleviate acute and chronic battlefield pain. Investigated solutions to replace or regenerate human cells, tissues, or organs to			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
restore or establish normal tissue function. Conducted applied research to identify therapeutic targets to restore visual, auditory, and vestibular function following traumatic injury. ***FY 2017 Plans:*** Military infectious diseases research continues to support multi-year studies in bacterial diseases research, and down-selecting promising efforts for further development. Releasing program announcements in wound infection to address critical research focus areas such as the ability to predict infection and better treatment options for infections with multi-drug resistant organisms (MDROs), and developing biomarker assays. Continuing efforts to maintain subject matter expertise in acute respiratory diseases. These efforts support the National Strategy for Combating Antibiotic Resistance. Military operational medicine research is collecting experimental data to validate whole-body computational models for the direct and indirect mechanism of blast brain injury and quantifying the biomechanical brain-tissue response. Determining optimal temporal spacing of repeated blast events to prevent cumulative effects. Collecting impulse noise experimental data to validate computational models of the inner ear to validate injury criteria. Developing comprehensive aircrew performance risk models of fatigue and hypoxia (oxygen deficiency). Monitoring the patterns of dietary supplement use in the Armed Forces and determining demographic and lifestyle factors associated with dietary supplement and caffeine use along with coincident motivating factors. Assessing the psychosocial and physiological factors affecting overuse injury susceptibility and career success of female Warriors. Conducting applied research to develop prevention skills training and interventions to prevent suicide behaviors. Completing studies that will inform opioid abuse risk reduction strategies. Delivering prototypes for Service member and family resilience building interventions. Investigating novel and evidence-based PTSD intervention adaptations (group, couples, web-based, etc.), selecting candidate biomarkers associated with treatment, and animal/human disease model development. Refining candidate biomarkers for exposure to inhaled or ingested toxic substances for establishing the probability of adverse health risk outcomes and continue refinement of a non-invasive tool for diagnosing pulmonary disease. Conducting research to refine metrics for optimized operational task performance in extreme environmental conditions. Combat casualty care hemorrhage research is investigating new diagnostic tools and continuing the development of treatments for severe hemorrhage following injury. Work focuses primarily on modulating inflammation and coagulopathy of trauma. Research is focusing on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Inflammatory modulation (controlling the body's response to harmful stimuli) and other research is focusing on the time period from 4 to 72 hours post-injury (related to prolonged field care scenarios). Treatments for extremity trauma and advanced wound stabilization are continuing. Treatments for prolonged field care scenarios that may enhance initial treatment and improve long term outcomes for burn, acute lung injury, and complex injuries to include maxillofacial injury are continuing.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Forward Surgical and Intensive Critical Care is studying the effectiveness of acute lifesaving interventions, how to improve survival for those in need of critical care on the battlefield and in acute stages of injury and during prolonged timeframes until reaching definitive care in the pre-hospital/hospital setting. En Route Care research is studying clinically-relevant testing standards for monitors in the transport environment and is developing new non-invasive monitoring technologies. Radiation health effects research is conducting non-clinical research to identify therapeutic candidates for acute radiation exposure and developing data to support preparation of technical data package requirements for investigational new drug applications. Research is focusing on evaluating candidate radioprotectants (prophylaxes that protect against cell damage caused by radiation) to determine their feasibility and practicality as candidate solutions to military needs. Clinical and rehabilitative medicine research is selecting the most promising candidate products to transition to technology development in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and sensory system injury. Supporting applied research in neuromusculoskeletal injuries to advance the diagnosis, treatment and rehabilitation outcomes after Service-related injuries. Identifying targets for therapies to alleviate acute, chronic, and battlefield pain and identifying strategies for addressing psychosocial aspects of pain management and pain-related substance abuse. Studying pain biomarkers to implement precision medicine approaches for pain management. Evaluating candidate reconstructive and regenerative technologies to replace or regenerate human cells, tissues, or organs to restore or establish normal tissue form and function of bone, skin, muscle, nerve, vasculature and connective tissue. Investigating the neuro-biology of tinnitus and hidden noise injury.			
FY 2018 Plans: Medical simulation and information sciences applied research will focus on researching pharmacodynamics and pharmacokinetics algorithms 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. The mathematical algorithms will focus on specific pharmacodynamics and pharmacokinetics as well as absorption, distribution, metabolism, and excretion of the pharmaceuticals and resuscitative options. Will support research on high fidelity tactile haptics (recreated sense of touch in simulated settings) to improve tactile sensation and resistance realism of virtual reality systems and mannequin based medical training systems. Military infectious diseases research will support previously initiated multi-year studies in bacterial diseases research, and will down-select promising efforts for further development. Multi-year studies initiated in FY17 through program announcements in wound infection will be supported to address critical research focus areas such as the ability to predict infection and better treatment options for infections with MDROs and development of biomarker assays for diagnosis of infection. Will develop novel and innovative therapeutics and delivery technologies for combat wound infections. Will maintain subject matter expertise in acute respiratory diseases. These efforts will support the National Strategy for Combating Antibiotic Resistance. Will maintain scientific			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
awareness and a capability to respond to emerging infectious diseases. Will partner with other entities to rapidly accelerate promising, innovative drug and vaccine solutions to combat emerging infectious diseases (e.g., Chikungunya, MERS, Zika). Military operational medicine research will continue to collect experimental data to validate whole-body computational models of the direct and indirect mechanism of blast brain injury. Will determine optimal temporal spacing of repeated blast events to prevent cumulative effects and analyze changes in brain injury biomarkers. Will collect impulse noise experimental data from volunteer subjects to validate computational models of inner ear injury. Will continue to refine comprehensive aircrew performance risk models of fatigue and hypoxia (oxygen deficiency). Will refine models of dietary supplement use patterns by Armed Forces members and determine demographic and lifestyle factors associated with dietary supplement and caffeine use along with risks and benefits of consumption. Will continue to assess the physical, psychosocial and physiological factors affecting overuse injury susceptibility and career success of female Warriors. Will continue to deliver prototypes for Service member and family resilience building interventions. Will begin studies aimed at delivering an evidence-based substance abuse prevention and training model and screening and compliance tools. Will begin to conduct research to deliver an evidence-based approach to reduce stigma and a training program to increase provider skill in assessing and treating suicidality. Will continue to investigate novel and evidence-based PTSD interventions. Will investigate adaptations in delivery of care toward the goal of increased accessibility. Will identify and develop candidate biomarker panels indicative of treatment-related improvement, and animal/human PTSD disease model development. Will analyze novel compounds and existing FDA-approved medications for potential use in treatment of PTSD. Will continue to refine candidate biomarkers of exposure to inhaled or ingested toxic substances for establishing the probability of adverse health risk outcomes, and continue refinement of a non-invasive tool for diagnosing pulmonary disease. Will continue to conduct research to refine metrics for optimized operational task performance in extreme environmental conditions. Combat casualty care hemorrhage research will investigate new diagnostic tools and will continue the development of treatments for severe hemorrhage following injury. Will continue to focus on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Will initiate studies of novel oxygen carriers for use in severe casualties where blood transfusions are not available. Inflammatory modulation and other research will continue its focus on the time period from 4 to 72 hours post-injury (related to prolonged field care scenarios). Tactical Combat Casualty Care (TCCC) will investigate novel approaches to enable field care of casualties when evacuation is delayed. Neurotrauma research will focus on precision medicine capabilities. This research will improve the characterization of TBI, lead to the development of targeted therapies, devices and clinical guidelines to improve the care provided to TBI casualties, investigate the impact of pre-injury conditions, genomics (study of genes in an organism), proteomics (study of all the proteins in a cell) and the environment on Service member response to treatment and recovery following TBI. This will lead to an understanding of the factors that influence and inform patient responsiveness to TBI therapeutic interventions, as well as the role of environmental and physiological factors that impact injury outcomes. Treatments for extremity trauma will continue to advance wound stabilization for prolonged field care scenarios that might enhance initial treatment and improve longer term outcomes.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Development of closed loop and decision assist technologies for burns, lung ventilation, organ support, and other complex injuries to include maxillofacial injury will continue. Pre-hospital Tactical Combat Casualty Care area will study the effectiveness of acute lifesaving interventions and how to improve survival for those in need of critical care on the battlefield, in acute stages of injury, and for those requiring prolonged times until reaching definitive care in the prolonged field care/pre-hospital/hospital setting. En Route Care research will continue to study clinically-relevant testing standards for monitors in the transport environment and develop new non-invasive monitoring technologies. Radiation health effects research will continue to conduct non-clinical research to identify therapeutic candidates for acute radiation exposure and develop data to support preparation of technical data package requirements for investigational new drug applications. Research will also focus on evaluating candidate preventative radioprotectants to determine their feasibility and practicality as candidate solutions to military needs. Objectives will include identifying mechanisms of action, efficacy and safety data in animal models for medical countermeasures for ARS. Clinical and rehabilitative medicine research will select the most promising candidate products to transition to technology development in the areas of neuromusculoskeletal injury, pain management, and regenerative medicine. Will support applied research in neuromusculoskeletal injuries to advance the diagnosis, treatment and rehabilitation outcomes after Service-related injuries. Will identify targets for therapies to alleviate acute, chronic, and battlefield pain and identify strategies for addressing psychosocial aspects of pain management and pain-related substance abuse. Will study pain biomarkers to implement precision medicine approaches for pain management. Will develop candidate reconstructive and regenerative technologies and methodologies for replacement or regeneration of human cells, tissues, or organs for restoration or establishment of normal tissue form and function of bone, skin, muscle, nerve, vasculature and connective tissue.			
Accomplishments/Planned Programs Subtotals	40.072	43.462	49.639

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Evaluate technical feasibility of potential solutions to military health issues. Implement models into data or knowledge and test in a laboratory environment. Technology Transition and Milestone A packages will be developed to facilitate product transition.

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Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, quarterly and annual status reports to include information on publications, intellectual property, additional funding support, and progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. The benchmark performance metric for transition of research conducted with applied research funding is the attainment of a maturity level that is at least Technology Readiness Level (TRL) 4, and typically TRL 5, or the equivalent for knowledge products. Products nearing attainment of TRL 5 will be considered for transition.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*	Project (Number/Name) 447A / *Military HIV Research Program (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
447A: *Military HIV Research Program (Army)*	14.959	7.462	7.438	7.794	-	7.794	9.022	9.654	9.847	10.044	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project conducts research on the human immunodeficiency virus (HIV), which causes acquired immunodeficiency syndrome (AIDS). This effort supports the Administration's priorities in the area of international scientific partnership in global health engagement. Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for clinical trials with global vaccine candidates. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals. This project is jointly managed through an Interagency Agreement between U.S. Army Medical Research and Materiel Command (USAMRMC) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health. This project contains no duplication of 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, and supports the principal area of Military Relevant Infectious Diseases to include HIV.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Military HIV Research Program	7.462	7.438	7.794
Description: This project conducts research on HIV, which causes AIDS. Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for future vaccine trials. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals.			
FY 2016 Accomplishments: FY16 accomplishments includes producing additional vaccine candidates for various world-wide subtypes and characterized these new sub-types and evaluated their capability to induce protective immune responses in non-human primates. In addition, one or more vaccine candidates were down-selected for use in safety studies in human volunteers.			
FY 2017 Plans: FY17 Plans include finalizing production and optimization of three new vaccine candidates from an East African region, characterizing these new sub-types and evaluating their capability to induce protective immune responses in non-human primates by using novel delivery systems, and down-selecting one vaccine candidate from an East African region for use in a human clinical trial to test for safety and immunogenicity (ability to invoke an immune response). In addition, an optimal delivery system containing a diverse mixture of antigens (substance that induces an immune response) for HIV subtypes A, C, D and E and test in non-human primates will be designed. This program continues to develop new clinical trial sites in Mozambique that will allow			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 447A / *Military HIV Research Program (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
scientists the opportunity to test future vaccine candidates against the predominant HIV subtype (C) circulating in this part of the world. ***FY 2018 Plans:*** In Fy18, plans are to develop and optimize methods of large scale production of new vaccine candidates for testing in Africa and Asia representing the breadth of HIV diversity. This program will produce and characterize these new vaccine candidates for use in pre-clinical and clinical testing as well as evaluate the vaccine candidates of interest to assess their capability to induce protective immune responses in non-human primates by using novel delivery systems. It will continue to down-select one or more vaccine candidates from non-human primate studies to test for safety and immunogenicity(ability to invoke an immune response) and optimize a delivery system containing a diverse mixture of antigens (substance that induces an immune response) for HIV subtypes A, B, C, D and E and test in non-human primates. New clinical trial sites will be identified and developed in Europe, Southeast Africa Asia and the US that will allow scientists the opportunity to test future vaccine candidates against predominant HIV subtypes circulating in this part of the world.			
Accomplishments/Planned Programs Subtotals	7.462	7.438	7.794

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

The program receives periodic funding from Division of AIDS of NIAID ranging from $10-20 million per year through an Interagency Agreement with USAMRMC.

D. Acquisition Strategy

N/A

E. Performance Metrics

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