Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	178.533	67.237	75.155	57.275	-	57.275	63.550	73.654	82.883	84.408	Continuing	Continuing
200A: *Congressional Special Interests*	70.883	25.303	16.904	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	0.000	3.150	2.860	-	2.860	2.142	1.857	1.949	1.989	Continuing	Continuing
306B: *Advanced Diagnostics & Therapeutics Research & Development (AF)*	6.912	2.708	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	0.000	1.728	1.757	-	1.757	1.987	2.025	2.066	2.107	Continuing	Continuing
306D: *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	0.000	0.000	1.728	1.758	-	1.758	1.988	2.026	2.066	2.108	Continuing	Continuing
372A: *GDF Applied Biomedical Technology*	92.328	32.677	43.579	43.462	-	43.462	49.639	58.724	67.148	68.357	Continuing	Continuing
447A: *Military HIV Research Program (Army)*	8.410	6.549	8.066	7.438	-	7.438	7.794	9.022	9.654	9.847	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 towards 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 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, 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 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, beginning in FY 2015, 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 2015, Congressional Special Interest funds were provided for Restore Core Research Funding Reduction. Because of the CSI annual structure, out-year funding is not programmed.

For the Air Force, this PE funds applied research which seeks to promote ‘omic’-informed personalized medicine, advanced diagnostic technologies and occupational toxicology with an emphasis on targeted prevention, diagnosis, and treatment. The delivery of pro-active, evidence-based, personalized medicine will improve health in Warfighters and beneficiaries by providing care that is specific to the situation and patient, to include preventing disease or injury, early and accurate diagnosis, and selection of appropriate and effective treatment. Personalized medicine will reduce morbidity, mortality, mission impact of illness/injury, and healthcare costs while increasing health and wellness of the AF population and efficiency of the healthcare system. This applied research supports multiple focus areas, each of which represents an identified barrier/gap which must be addressed for successful implementation of ‘omic’-informed personalized medicine. Focus areas for applied research include knowledge generation research; ethical legal and social issues/policy research; bioinformatics research; educational research; research for development of advanced genomic diagnostic system. For efforts supported by this program element, research will be pursued with the intent to support solutions that answer Air Force specific needs. During this process, the efforts of other government agencies in those areas will be assessed to avoid redundancy.

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency					Date: February 2016
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*		R-1 Program Element (Number/Name) PE 0602115DHA / *Applied Biomedical Technology*			
B. Program Change Summary ($ in Millions)	**FY 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**
Previous President's Budget	47.898	58.251	68.797	-	68.797
Current President's Budget	67.237	75.155	57.275	-	57.275
Total Adjustments	19.339	16.904	-11.522	-	-11.522
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	25.303	16.904			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-1.785	-			
• SBIR/STTR Transfer	-4.179	-			
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-8.797	-	-8.797
• Restore USUHS Breast, GYN, and Prostate Cancer Centers of Excellence	-	-	-3.350	-	-3.350
• Rebalance Joint Program Committees	-	-	0.625	-	0.625

Congressional Add Details ($ in Millions, and Includes General Reductions)	**FY 2015**	**FY 2016**
Project: 200A: *Congressional Special Interests*		
Congressional Add: *426A – CSI - Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)*	0.000	5.833
Congressional Add: *462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)*	19.620	10.000
Congressional Add: *469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army)*	4.941	1.071
Congressional Add: *469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force)*	0.742	0.000
Congressional Add Subtotals for Project: 200A	25.303	16.904
Congressional Add Totals for all Projects	25.303	16.904

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).

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
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 2016: Restore core research funding to the DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$16.904 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-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
200A: *Congressional Special Interests*	70.883	25.303	16.904	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

The FY 2015 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 2015	FY 2016
Congressional Add: 426A – CSI - Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)	0.000	5.833
FY 2015 Accomplishments: N/A		
FY 2016 Plans: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest program aimed to execute studies that inform the development of strategies to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, veterans, family members, caregivers, and communities. A key priority of the TBI/PH applied research program was to complement ongoing DoD 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 (identification of the nature and cause of an illness), treatment, and rehabilitation. Program announcements, programmatic reviews, Service-requested nominations, and ongoing studies that would benefit from program acceleration have been incorporated to address these priorities and gather proposals. In the area of TBI, researchers performed investigations to find a universally-agreed upon concussion grading system, and continued experiments into the effects of penetrating injuries on the brain and experiments on the effects of blasts on the brain. Proposals were solicited in the areas of blast-induced hyper-acceleration upon the generation of TBI and the role of inflammation in spreading TBI damage. Multiple awards relevant to combat casualty care were made including development of a large animal model of penetrating ballistic brain injury and development of metrics to define concussion and grade TBI. In the area of psychological health, researchers performed investigations to diagnose, prevent, and reduce symptoms of PTSD, and understand predictors of violence among workers in military settings.		
Congressional Add: 462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)	19.620	10.000
FY 2015 Accomplishments: FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0602115. Funds supported applied research for military infectious		

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016
diseases, military operational medicine, combat casualty care, radiation health effects and clinical and rehabilitative medicine (Project 372A). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0602115. Funds supported applied research for military infectious diseases, military operational medicine, combat casualty care, radiation health effects and clinical and rehabilitative medicine (Project 372A).		
Congressional Add: 469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0602115. Funds supported research in Military HIV Research (Project 447A) and Combating Antibiotic Resistant Bacteria (Project 246A). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0602115. Funds supported research in Military HIV Research (Project 447A) and Combating Antibiotic Resistant Bacteria (Project 246A).	4.941	1.071
Congressional Add: 469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0602115. Funds supported Air Force research in Advanced Diagnostics and Therapeutics (Project 306B). ***FY 2016 Plans:*** No Funding Programmed.	0.742	0.000
Congressional Adds Subtotals	25.303	16.904

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,

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115DHA / *Applied Biomedical Technology*	**Project (Number/Name)** 200A / *Congressional Special Interests*

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 (S&T) 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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
246A: *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	0.000	0.000	3.150	2.860	-	2.860	2.142	1.857	1.949	1.989	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 that simultaneously 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 2015	FY 2016	FY 2017
Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	0.000	3.150	2.860

Description: Initiate 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) initiates partnerships with external collaborators to develop/co-develop new potential antibacterial treatment therapeutics.

FY 2015 Accomplishments:

Established the research program and initiated the assessment of antibacterial programs from companies that have exited the commercial antibacterial drug discovery (direct contact and literature publications) market for potential leads, identified and hired staff, developed desired therapeutic product profile criteria and DoD-focused Target Product Profiles to meet military requirements, and evaluated chemical hits/leads with development potential.

FY 2016 Plans:

Continue applied research to evaluate 2-4 chemical compounds for antibacterial effectiveness in the laboratory and in animals, and complete market analysis of external antibiotic programs to discover small molecules that are in early drug discovery (pre-clinical,1-4 years away from advanced development) that may be expanded or elaborated. Assays are under evaluation to assess potential lead candidates, synthesize key chemical compounds and newly designed lead optimization chemical compounds,

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
begin to establish in vivo (living organism) model standards, and evaluate late stage external programs that could potentially treat military relevant resistant bacteria. Efforts are being made to establish agreements where intellectual property rights are involved. ***FY 2017 Plans:*** Will establish sustainable research efforts designed to evaluate viable small molecule candidate antibacterial agents for planned development for the DoD and Public Health benefit. Will continue expansion of market analysis of external antibiotic programs, compound optimization, and Investigational New Drug-enabling study coordination. Will obtain agreements if intellectual property rights are owned by existing companies or complete partner agreements in order to explore and co-develop new antibiotics leads. Will conduct 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 evaluate one or two viable compounds by FY 2020 that can be transitioned into advanced development.			
Accomplishments/Planned Programs Subtotals	0.000	3.150	2.860

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
306B: *Advanced Diagnostics & Therapeutics Research & Development (AF)*	6.912	2.708	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 2015	FY 2016	FY 2017
Title: Advanced Diagnostics & Therapeutics Research & Development (AF)	2.708	0.000	0.000

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 2015 Accomplishments:

Established genetic marker research data, tissue and specimen repository for future studies. Elucidated the genetic epidemiology of T2D in the MHS population, providing evidence of specific single nucleotide polymorphisms associated with an enhanced risk of future diabetes and prediction of future disease, far in advance of actual disease onset, to reduce disease burden and preserve the military readiness mission, especially in younger adults. Evaluated, optimized and validated sophisticated advanced diagnostic technologies, including automated nucleic acid extraction for complex matrices, DNA next generation sequencing and Real-Time Polymerase Chain Reaction (PCR) technology for RNA and DNA pathogens of both viral and bacterial etiology, advanced molecular biology procedures, bio-informatics, and connectivity and communication endeavors to provide commanders at all levels the information needed to make time-critical disease prevention and control decisions, on the ground where outbreaks occur. Real-Time polymerase chain reaction assays optimized and utilized in sample characterization at the Center for Advanced Molecular Detection clinical repository include Influenza A (H1, H3, H5a and b), Influenza B, Respiratory Syncytial Virus A and B, Human Parainfluenza Virus 1, 2, and 3, Human Metapneumovirus, Rhinovirus, Enteroviruses, Adenovirus (and human Adenovirus subtyping), Human Metapneumovirus, Bocavirus, L. pneumophila, H. influenzae, Streptococcus pyogenes, Streptococcus

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
pneumonia, Bordetella pertussis (I) and parapertussis (II), Chlamydia pneumonia and Mycoplasma pneumonia. Achieved IRB approval for initiation of FY16 protocols. Completed toxicological/functional testing of three organ cell lines. ***FY 2016 Plans:*** No Funding Programmed. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	2.708	0.000	0.000

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
306C: *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	0.000	0.000	1.728	1.757	-	1.757	1.987	2.025	2.066	2.107	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 2015	FY 2016	FY 2017
Title: Core Adv Diagnostics & Epigenomics Applied Research (AF)	0.000	1.728	1.757

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 2015 Accomplishments:
No funding programmed.

FY 2016 Plans:
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

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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 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. Total FY16 requirements cost is $4.500M; FY16 UFR = $2.772M ***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. Total FY17 requirement is $3.757M; FY17 UFR = $2.000M			
Accomplishments/Planned Programs Subtotals	0.000	1.728	1.757

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.)

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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)*

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
306D: *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	0.000	0.000	1.728	1.758	-	1.758	1.988	2.026	2.066	2.108	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 2015	FY 2016	FY 2017
Title: Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)	0.000	1.728	1.758

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 2015 Accomplishments:

No funding programmed.

FY 2016 Plans:

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. Develop passive dosimeters to support 24/7 exposure monitoring. Expand toxicological/functional testing of organ cell lines, development of new organ system cell lines and build library of multiple chemical exposure. Continue to develop environmental biosurveillance procedures for monitoring metagenomic drift within field hospitals and forward bases.

FY 2017 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
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. Explore capture of assorted biological signatures to characterize health and physiological status.			
Accomplishments/Planned Programs Subtotals	0.000	1.728	1.758

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
372A: *GDF Applied Biomedical Technology*	92.328	32.677	43.579	43.462	-	43.462	49.639	58.724	67.148	68.357	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 (JPCs) in the following areas: 1- Military infectious diseases research is developing protection and treatment products for military relevant infectious diseases. Applied research is conducted in the task areas of bacterial diseases, diagnostics development, and viral diseases. 2- Military operational medicine 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. Applied research is conducted in the task areas of musculoskeletal injury; brain health and performance risk; behavioral health, wellness and resilience; warfighter physical performance; nutrition and weight balance; fatigue countermeasures, psychiatry and clinical psychology disorders; auditory and vestibular performance, injury and protection; blunt, blast and accelerative injury; environmental toxicant exposure; and aircrew health and performance. 3- Combat casualty care research is focused on optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through enroute and facility care. Applied research is conducted in the task areas of hemorrhage, shock, and coagulopathy of trauma; traumatic brain injury (TBI) neurotrauma and brain dysfunction; treatments for extremity trauma, tissue injury, craniomaxillofacial injury, lung injury, and burns; pre-hospital tactical combat casualty care; and enroute care. 4- Radiation health effects applied research supports tasks for the development of radiation medical countermeasures, to include therapeutic candidates for acute radiation once exposure has occurred, and preventative treatment prior to exposure (radioprotectants). 5- Clinical and rehabilitative medicine is developing knowledge and materiel products to reconstruct, rehabilitate, and provide care for injured Service members. Applied research is conducted in the task areas of neuromusculoskeletal rehabilitation, pain management, regenerative medicine, and sensory systems.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: GDF Applied Biomedical Technology	32.677	43.579	43.462
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 2015 Accomplishments: Military infectious diseases research supported multi-year studies in bacterial diseases; progressed in development of four novel therapeutics (e.g., drugs) to mitigate wound infection and biofilm processes, pursued development of tools and practices for the detection/prevention of microbial infections in wounds and/or guide clinical wound management, performed confirmatory laboratory studies and initial animal studies to demonstrate drug potency, and demonstrated biomarker (biological indicator of			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
health outcomes and disease) accuracy and degree of confidence in identifying pathogens. Efforts to maintain subject matter expertise in acute respiratory diseases and diagnostic systems for infectious diseases were continued. Military operational medicine research established animal models to determine risk of performance decrement resulting from repeated low level blast exposure, developed military relevant clinical and functional assessments to determine return to duty after musculoskeletal injury, and developed strategies to model human middle ear dynamics when subjected to impulse noises, which will lead to validating hazardous impulse noise exposure standards. Continued studies aimed at establishing an animal model for dependency and withdrawal associated with prescription drugs and substance abuse. Continued research to understand how to support family resilience and behavioral health during deployment and reintegration to inform intervention development. Continued studies focused on selecting candidate biomarkers for objective Posttraumatic Stress Disorder (PTSD) screening, pilot research evaluating novel PTSD intervention strategies, and adaptations of existing evidence-based psychotherapies for PTSD treatment. Developed a reporting system for adverse events associated with dietary supplement use, and developed computational models that can predict bone and muscle health status. Established risk factors for heat injury susceptibility, studied select candidate biomarkers for inhalation exposure to toxic substances, and conducted dehydration studies to select stress biomarkers of hydration status. These research efforts supported the Precision Medicine Initiative. Combat casualty care hemorrhage research made progress toward supporting studies assessing the effectiveness of Valproic Acid, a FDA-approved anti-seizure drug, and ethinyl estradiol to increase survival of severe hemorrhage. Established effects of modulating the inflammatory response associated with hemorrhagic shock and trauma, and examined specific mechanisms that may be involved in coagulopathy of trauma. TBI neurotrauma research made progress in developing TBI biomarkers and screening tools. Treatments for extremity trauma addressed burn, acute lung injury, and enhanced healing of complex injuries of the face, extremities, groin and pelvis. Pre-hospital tactical combat research included resuscitative interventions through seamless critical care. The enroute care task made significant advances to understand and improve field management and safe air transport of patients with head and spine injuries. Radiation health effects research pursued 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 address research data gaps and to characterize several compounds with potential to mitigate or prevent Acute Radiation Syndrome (ARS) resulting from lethal doses of radiation. The research aimed to determine mechanisms of action, effectiveness, and safety in animal models in the development of therapeutics for ARS hematopoietic (bone marrow) sub-syndrome. Clinical and rehabilitative medicine research conducted applied research in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and/or sensory (hearing and sight) system traumatic injury. The neuromusculoskeletal injury portfolio examined the impact of biopsychosocial effects on rehabilitation, improved the current technology available for			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
residual limb-device interface, and developed objective metrics for device prescription and training. In pain management, research was conducted that studied enhanced chronic pain management using receptor antagonists (agents that block biochemical responses). Regenerative medicine research studied novel tissue-engineered nerve grafts for currently unrepairable nerve injury, and treatment for re-innervated (restored nerve function) muscle. Sensory systems research studied pre-clinical testing of sustained release drugs to prevent blinding complications following eye injury, and developed therapeutic drugs for hearing restoration after noise induced hearing loss. ***FY 2016 Plans:*** Military infectious diseases research supports multi-year studies in bacterial diseases, and continues the development efforts of four antibacterial projects and two projects for the detection of microbial infections in wounds. Studies are 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 are being evaluated for further development. Continue efforts to maintain subject matter expertise in acute respiratory diseases. These studies are in alignment with the National Strategy for Combating Antibiotic Resistance. Military operational medicine research is validating repeated low level blast injury animal models compared to occupational blast exposures, developing computational models of the nonlinear middle ear function to establish hearing injury criteria, developing improved clinical strategies to determine safe return to duty after severe musculoskeletal injury, and characterizing the effects of hypoxia (oxygen deficiency) and fatigue on aircrew performance in rotary and fixed wing aircraft. Conducting applied research to develop strategies for building Service member and family resilience and to support successful reintegration following deployment. Continuing to establish associations between military service, deployment, risk and protective factors, and psychological and physiological health problems to inform development of policies and guidelines. Continuing 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. Developing interventions for sustainable weight loss in military families, and continuing the development of computational models that can predict bone and muscle health status. Performing studies of risk factors for heat injury susceptibility and develop a non-invasive tool for diagnosing pulmonary disease. C Conducting studies for novel mitigation and treatment strategies and biomarker detection to optimize physiological performance and protect against multi-environmental injury. Refining biomarkers of environmental exposure to toxic substances inhaled or ingested that will be used for establishing the probability of adverse health risk outcomes. Conducting studies to define metrics for optimized performance in extreme environmental conditions.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Combat casualty care hemorrhage research continues to search for new diagnostic tools and the development of treatments for abnormal hemorrhage following injury. Work focuses primarily on inflammatory modulation (determining the efficacy of complement inhibitors in swine) and coagulopathy of trauma (computational and mathematical modeling of coagulopathy of trauma). Neurotrauma research is further developing and investigating TBI biomarkers and screening tools for far-forward medical evaluation of warriors. Forward Surgical and Intensive Critical Care is studying 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 address burn, acute lung injury, and enhanced healing of complex injuries of the face, extremities, groin and pelvis. Tissue injury research is also addressing wound stabilization in the prolonged field care scenario and will continue to specifically address the need for a maxillofacial stabilization dressing. The enroute care research is studying 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 is continuing strategies for protection, mitigation, and treatment of radiation-induced tissue injury due to high doses of radiation exposure. Conduct 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 address bone marrow (hematopoietic) and gastrointestinal effects. Pulmonary effects of radiation exposure are also being examined. Based on research accomplishments, compounds are being evaluated as potential candidates for transition toward advanced development. Additional efforts are evaluating 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 is pursuing down-selection of candidate products for transition to technology development in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and/or sensory (hearing, sight, and balance) system traumatic injury. Conducting applied research in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation after Service-related injuries. Studying the effectiveness of leading solutions to alleviate acute and chronic battlefield pain, investigating solutions to replace or regenerate human cells, tissues, or organs to restore or establish normal tissue function, and conducting applied research to identify therapeutic targets to restore visual, auditory, and vestibular function following traumatic injury.			
FY 2017 Plans: Military infectious diseases research will support multi-year studies initiated in FY 2014 and FY 2015 in bacterial diseases research, and will down-select promising efforts for further development. Program announcements in wound infection will be released to address critical research focus areas such as the ability to predict infection and better treatment options for infections			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
with multi-drug resistant organisms. Will continue efforts to maintain subject matter expertise in acute respiratory diseases. These studies will support the National Strategy for Combating Antibiotic Resistance. Military operational medicine research will collect experimental data to validate whole-body computational models for the direct and indirect mechanism of blast brain injury and quantify the biomechanical brain-tissue response, determine optimal temporal spacing of repeated blast events to prevent cumulative effects, collect impulse noise experimental data to validate computational models of the inner ear to validate injury criteria, and will develop comprehensive aircrew performance risk models of fatigue and hypoxia (oxygen deficiency). Will continue to monitor the patterns of dietary supplement use in the Armed Forces and determine demographic and lifestyle factors associated with dietary supplement and caffeine use along with coincident motivating factors. Will assess the psychosocial and physiological factors affecting overuse injury susceptibility and career success of female Warriors. Will conduct applied research to develop prevention skills training and interventions to prevent suicide behaviors. Will complete studies that will inform opioid abuse risk reduction strategies. Will deliver prototypes for Service member and family resilience building interventions. Will continue 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. Will continue to refine 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. Will 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. Work focuses primarily on modulating inflammation (determining the efficacy of complement inhibitors in swine) and coagulopathy of trauma (computational and mathematical modeling of coagulopathy of trauma). Will begin to focus on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Inflammatory modulation and other work will begin to focus on the time period from 4 to 72 hours post-injury (related to prolonged field care scenarios). Neurotrauma research will further develop identified TBI biomarkers and screening tools for far-forward medical evaluation of warriors; develop clinical tools/treatments to minimize the progression of TBI at point of injury; and provide capabilities for the treatment, management and monitoring of moderate and severe head injuries in accordance with Advanced Trauma Life Support (ATLS) protocols in a far forward environment. 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 for burn, acute lung injury, and complex injuries to include maxillofacial injury. Forward Surgical and Intensive Critical Care will study the effectiveness of acute lifesaving interventions and how to improve survival for those in need of critical care on the battlefield and in acute stages of injury and for those requiring prolonged times until reaching definitive care in the pre-hospital/hospital setting. Enroute care research will study clinically-relevant testing standards for monitors in the transport environment and will develop new non-invasive monitoring technologies.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
Radiation health effects research will conduct non-clinical research to identify ARS therapeutic candidates for acute radiation exposure and develop data to support preparation of technical data package requirements, as detailed in the Code of Federal Regulations, Chapter 21, Part 312. Research will also focus on evaluating candidate radioprotectants (prophylaxes) to determine their feasibility and practicality as candidate solutions to military needs. 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 guide 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 evaluate 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.			
Accomplishments/Planned Programs Subtotals	32.677	43.579	43.462

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.

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: PB 2017 Defense Health Agency			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
447A: *Military HIV Research Program (Army)*	8.410	6.549	8.066	7.438	-	7.438	7.794	9.022	9.654	9.847	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 US Army Medical Research and Materiel Command (USAMRMC) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). 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 2015	FY 2016	FY 2017
Title: Military HIV Research Program	6.549	8.066	7.438

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 2015 Accomplishments:
Completed production of additional vaccine candidates for various world-wide subtypes. Developed improved methods to evaluate immune responses to selected HIV vaccine candidates in non-human primates. Analyzed host genetic factors related to HIV acquisition and disease progression in acute HIV infection to inform vaccine development. Completed down-selection of best candidates for use in Phase 1 safety studies in human volunteers.

FY 2016 Plans:
Continue to produce additional vaccine candidates for various world-wide subtypes. Characterize these new sub-types and evaluate their capability to induce protective immune responses in non-human primates. Down-select one or more vaccine candidates for use in safety studies in human volunteers.

FY 2017 Plans:
Will finalize production and optimization of three new vaccine candidates from an East African region. Will characterize these new sub-types and evaluate their capability to induce protective immune responses in non-human primates by using novel delivery

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
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 2015	FY 2016	FY 2017
systems. Will down-select 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). Will also design 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 continue to develop new clinical trial sites in Mozambique that will allow scientists the opportunity to test future vaccine candidates against the predominant HIV subtype (C) circulating in this part of the world.			
Accomplishments/Planned Programs Subtotals	6.549	8.066	7.438

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 (IIPT) and in-process reviews (IPR).