Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Defense Health Program											Date: March 2014	
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*							
COST ($ in Millions)	**Prior Years**	**FY 2013**	**FY 2014**	**FY 2015 Base**	**FY 2015 OCO #**	**FY 2015 Total**	**FY 2016**	**FY 2017**	**FY 2018**	**FY 2019**	**Cost To Complete**	**Total Cost**
Total Program Element	67.160	51.405	60.452	47.898	-	47.898	55.101	65.640	72.895	73.840	Continuing	Continuing
200A: *Congressional Special Interests*	34.750	21.133	15.000	-	-	-	-	-	-	-	-	-
306B: *Advanced Diagnostics & Therapeutics Research & Development (Air Force)*	3.377	-	3.535	2.968	-	2.968	3.456	3.515	3.975	3.038	Continuing	Continuing
372A: *GDF Applied Biomedical Technology*	29.033	30.272	33.192	37.755	-	37.755	43.579	53.913	59.631	63.703	Continuing	Continuing
447A: *Military HIV Research Program (Army)*	0.000	-	8.725	7.175	-	7.175	8.066	8.212	9.289	7.099	Continuing	Continuing

The FY 2015 OCO Request will be submitted at a later date.

A. Mission Description and Budget Item Justification

For the Guidance for Development of the Force - Applied Biomedical Technology: This applied research funding is to refine concepts and ideas into potential solutions to military health and performance problems, with a view towards evaluating technical feasibility. Included are studies and investigations leading to candidate solutions that may involve use of animal models for testing in preparation for initial human testing. Research in this program element is designed to address the following: areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and the strategy and initiatives described in the Quadrennial Defense Review. Program development is peer-reviewed and fully coordinated with all 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. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program (DHP) Research, Development, Test and Evaluation (RDT&E) funding. Research supported by this program element includes hemorrhage (bleeding) control, resuscitation and blood products; forward surgical and intensive critical care; en route care; treatments for extremity trauma, tissue injury, cranio-maxillofacial injury (injury to the head, face, jaw, and mouth), lung injury, and burns; rehabilitation; diagnosis and treatment of brain injury; operational health and performance; radiation countermeasures; and psychological health and well-being for military personnel and families. Applied research in military infectious diseases focuses on wound infection prevention, antimicrobial countermeasures and diagnostic systems for infectious diseases. As research efforts mature, the most promising efforts will transition to technology development (PE 0603115HP) or advanced concept development (PE 0604110HP) funding.

For the Army Medical Command, beginning in FY14, the military HIV research program funding is transferred from the Army to the Defense Health Program. Work in this area includes refining improved identification methods to determine genetic diversity of the virus, preclinical work in laboratory animals including non-human primates to identify candidates for global HIV-1 vaccine, and evaluating and preparing overseas sites for clinical trials with these vaccine candidates.

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Defense Health Program	Date: March 2014
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0602115HP *I Applied Biomedical Technology*

The Army Medical Command also received DHP Congressional Special Interest (CSI) research funding focused on Peer-Reviewed Traumatic Brain Injury and Psychological Health Research. 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 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.

B. Program Change Summary ($ in Millions)	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO	FY 2015 Total
Previous President's Budget	42.188	46.761	66.699	-	66.699
Current President's Budget	51.405	60.452	47.898	-	47.898
Total Adjustments	9.217	13.691	-18.801	-	-18.801
• Congressional General Reductions	-0.086	-			
• Congressional Directed Reductions	-12.063	-			
• Congressional Rescissions	-	-			
• Congressional Adds	22.988	15.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.622	-1.309			
• Reductions related to Departmental Efficiencies - Project 306B	-	-	-0.742	-	-0.742
• Reductions related to Departmental Efficiencies - Project 372A	-	-	-16.265	-	-16.265
• Reductions related to Departmental Efficiencies - Project 447A	-	-	-1.794	-	-1.794

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2013	FY 2014
Project: 200A: *Congressional Special Interests*		
Congressional Add: *426A – Traumatic Brain Injury and Psychological Health (TBI/PH) (Army)*	21.133	15.000
Congressional Add Subtotals for Project: 200A	21.133	15.000

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Defense Health Program	Date: March 2014
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0602115HP *I Applied Biomedical Technology*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2013	FY 2014
Congressional Add Totals for all Projects	21.133	15.000

Change Summary Explanation

FY 2013: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115-Applied Biomedical Technology (-$1.622 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+$1.622 million).

FY 2013: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$22.988 million).

FY 2013: General Congressional Reductions to DHP RDT&E, PE 0602115-Applied Biomedical Technology (-$0.086 million).

FY 2013: Congressional Directed Reductions (Sequestration) to DHP RDT&E, PE 0602115-Applied Biomedical Technology (-$12.063 million).

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115-Applied Biomedical Technology (-$1.309 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+$1.309 million).

FY 2014: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$15.000 million).

FY 2015: Reduces non-combat injury research funding in order to focus and continue the pace of progress in critical and high priority research areas for DHP RDT&E, PE 0602115-Applied Biomedical Technology (-$18.801 million).

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program			Date: March 2014
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*	Project (Number/Name) 200A / *Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
200A: *Congressional Special Interests*	34.750	21.133	15.000	-	-	-	-	-	-	-	-	-

The FY 2015 OCO Request will be submitted at a later date.

A. Mission Description and Budget Item Justification

For FY13, DHP Congressional Special Interest (CSI) funding is directed to stimulate innovative research through a competitive, peer-reviewed research program focused on peer-reviewed traumatic brain injury and psychological health research. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
Congressional Add: 426A – Traumatic Brain Injury and Psychological Health (TBI/PH) (Army)	21.133	15.000
FY 2013 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest program aims 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. Project funding was divided into basic science, applied research, technology development and concept advanced development efforts. A key priority of the TBI/PH research program is to complement ongoing DoD efforts to ensure the health and readiness of our military forces by promoting a better standard of care for post traumatic stress disorder (PTSD) 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. In addition, a new Department of Veterans Affairs/Department of Defense (VA/DoD) neurotrauma consortium program announcement was released to form a five-year, multi-university consortium to discover mechanisms of treatment and the long-term effects of TBI and its relationship to chronic traumatic encephalopathy (CTE), a degenerative brain disease diagnosed properly after death in patients with a history of multiple concussions. 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 on methods to prevent and reduce symptoms of PTSD, to understand how the deployment cycle affects marriage quality and stability, workplace violence in the		

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 200A / *Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
military, and alcohol use and co-occurring PTSD. Furthermore, a new VA/DoD consortium to alleviate PTSD program announcement was released to address PTSD treatment needs. ***FY 2014 Plans:*** This Congressional Special Interest project will support Traumatic Brain Injury and Psychological Health research.		
Congressional Adds Subtotals	21.133	15.000

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 annual 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 (S&T) governance.

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program			Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 306B / *Advanced Diagnostics & Therapeutics Research & Development (Air Force)*	

COST ($ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
306B: *Advanced Diagnostics & Therapeutics Research & Development (Air Force)*	3.377	-	3.535	2.968	-	2.968	3.456	3.515	3.975	3.038	Continuing	Continuing

The FY 2015 OCO Request will be submitted at a later date.

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 2013	FY 2014	FY 2015
Title: Advanced Diagnostics & Therapeutics Research & Development (Air Force)	-	3.535	2.968

Description: 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.

FY 2013 Accomplishments:

Continue to support regenerative medicine program at Armed Forces Institute of Regenerative Medicine. Perform AF Surgeon General directed deep dive on Health as a National Strategic Imperative/Lifestyle Medicine. Assess initial results of nanotechnology research projects at the Massachusetts Institute of Technology as they relate to Enroute Care and Expeditionary Medicine missions. Transfer the leadership of the continuing forum to educate leaders on futures based thinking from AFMS/SG to OSD/HA. Continue research on the development of a global events tool. Sponsor symposium on translating genomic medicine through provider education. Continue the genomics clinical utility study. Implement a milestone approach for Personalized Medicine/Genomic Medicine. Continue to leverage joint diagnostic efforts to meet AF mission requirements. Transition findings / outcomes of intramural project to identify and characterize epigenetic biomarkers of stress caused by high altitude conditions in a collaborative clinical translational research project in collaboration with the Uniformed Services University of the Healthcare Sciences (USUHS) to clinical practice / practice guidelines.

FY 2014 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 306B / *Advanced Diagnostics & Therapeutics Research & Development (Air Force)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Continue to support regenerative medicine program at Armed Forces Institute of Regenerative Medicine. Perform AF Surgeon General directed deep-dive on topic to be determined; develop a database library of submissions and topics for further use within the AFMS community. Complete nanotechnology research projects at the Massachusetts Institute of Technology. Analyze outcomes of symposium. Complete genomics clinical utility study. Continue to mature the global events tool. ***FY 2015 Plans:*** Continue FY14 actions.			
Accomplishments/Planned Programs Subtotals	-	3.535	2.968

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 2015 Defense Health Program			Date: March 2014
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*	Project (Number/Name) 372A / *GDF Applied Biomedical Technology*	

COST ($ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
372A: *GDF Applied Biomedical Technology*	29.033	30.272	33.192	37.755	-	37.755	43.579	53.913	59.631	63.703	Continuing	Continuing

The FY 2015 OCO Request will be submitted at a later date.

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 to military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development. Applied research will be conducted in the general categories of trauma, polytrauma (multiple traumatic injuries) and blast injury, rehabilitation, diagnosis and treatment of brain injury, radiation countermeasures, operational health and performance, and psychological health and well-being for military personnel and families. Applied research in traumatic brain injury (TBI) focuses on diagnosis and treatment, disentanglement of combat stress injuries, and TBI in evaluations and clinical management. Trauma, polytrauma and blast injury applied research focuses on control of bleeding, tissue viability (survival potential of a tissue or organ), diagnosis and life support, cranio-maxillofacial (head, neck, face, and jaw) injury, evacuation applications and practices, forward surgical applications, blast injury models and performance standards for protection systems, blast induced brain injury models, diagnostics and metrics for hearing loss and protection, blast exposure and breaching (process used to force open closed and/or locked doors), scar contracture (tightening of muscle, tendons, ligaments or skin that prevents normal movement), treatment of ocular and visual system traumatic injury, rapid screening of fresh whole blood, wound infection prevention and management, and antimicrobial (a substance that kills or inhibits the growth of microorganisms) countermeasures.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: GDF Applied Biomedical Technology	30.272	33.192	37.755
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 2013 Accomplishments: Military infectious diseases research supported multi-year studies, initiated in FY11 and FY12, in development of antibacterial agents for biofilms (a slime surface aggregate of microorganisms in which cells adhere to each other on a surface) and multidrug-resistant organisms (MDROs), detection of MDROs, and biomarker (indicator of biological state or the past or present existence of a particular type of organism or molecule) and diagnostic assay (test) development for down selection and transition of promising efforts to medical technology development. Military operational medicine researchers performed studies on: validation of the predictive capacity of biomarkers (indicator of biological state or the past or present existence of a particular type of organism or molecule) of lung disease identified			

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
in pulmonary (pertaining to the lungs) samples from deployed Warfighters exposed to potentially toxic particulate material; development of a scoring system for small airways disease to standardize interpretation of lung biopsies (sampling of tissue or cells for examination); analysis of mineral, fiber, and particulate matter components in post-deployment lung tissue samples compared to controls; determination of psychological, interpersonal, and social factors and assets that predict a resilient trajectory following exposure to adversity during the deployment cycle; evaluation of nutrition and dietary supplement benefits to physiological (human mechanical, physical and biochemical functions) health; evaluation of specific factors that may modify the causal relationship between individual factors such as demographics, military occupational specialties and prior health, family factors and deployment factors on diagnosis of mental illness and intra-family violence; establishment of recommendations to enhance the successful implementation of future interventions for mental illness and intra-family violence; and identification of specific targets with relevance for drug treatment development in PTSD that will lead to the development of a pharmacological (drug) treatment for PTSD. Combat casualty care researchers continued studies, initiated in FY11 and FY12, in hemorrhagic (bleeding) shock and trauma, TBI biomarkers (indicator of biological state or the past or present existence of a particular type of organism or molecule)and screening tools, en route care, permanent pathology caused by mild and moderate TBI and combination drug therapies. Researchers started applied technology research of selected candidate products identified in basic research and issued a program announcement for further applied research. Radiation health effects and countermeasure research addressed advances in the development of small molecules, protein, and cellular-based strategies for protection and mitigation of radiation-induced tissue injury due to high doses of radiation exposure. Completed animal studies in mice and non-human primates, which showed promising results mitigating gastrointestinal and lung injury resulting from lethal doses of radiation. Clinical and rehabilitative medicine continued studies in neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury, pain management, regenerative medicine, and/or sensory system traumatic injury to identify and evaluate candidate approaches for incorporation into restoration and rehabilitation strategies and medical products. Specific focus areas included: neuromusculoskeletal injury rehabilitation strategies and devices, prosthetics (artificial device that replaces a missing body part lost through trauma, disease, or congenital conditions), and the prevention of heterotopic ossification (growth of bone in abnormal places like soft tissue); novel therapeutics and devices for pain management; regenerative medicine-based approaches for limb (extremities) and digit (fingers, thumbs and toes) salvage, cranio-maxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, genitourinary (system of the reproductive and urinary organs) restoration and addressing compartment syndrome (muscle and nerve damage due to swelling post-injury); and restoration and rehabilitation of			

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015

sensory system injury, including vision, hearing and balance injury and dysfunction. The majority of sensory system efforts were postponed to FY14 due to sequestration.

FY 2014 Plans:

Military infectious disease research is continuing development of the rapid Nucleic Acid Test screening of donor derived fresh whole blood in emergency settings for infectious diseases. Down selection of the Nucleic Acid Testing platform is being conducted in Q4FY14. A program announcement for FY14 is soliciting novel proposals in the areas of wound infection prevention and management drug discovery to combat multiple-drug resistant bacterial infections and to identify host and pathogen biomarkers to detect bacterial infections in wounds.

Military operational medicine researchers are conducting studies, initiated in FY12 and FY13, in nutrition and dietary supplements, Warfighter performance and sustainment in extreme environments (such as extreme heat, cold, or altitude), return to duty/medical standards criteria, blast injury models and performance standards for protections systems, diagnostics and metrics for hearing loss and protection, alcohol and substance abuse, diagnosis of deployment-related psychological health problems, diagnosis of post-traumatic stress disorder (PTSD), military family and Warfighter resilience, suicide prevention, pulmonary (pertaining to the lungs) health in the deployed environment, and blast exposure during breaching (process used to force open closed and/or locked doors). Program announcements are soliciting proposals in the areas of physiological (human mechanical, physical and biochemical functions) health, injury prevention and reduction, psychological health, and environmental health and protection.

Combat casualty care research is supporting multi-year studies, initiated in FY12 and FY13, in hemorrhagic (bleeding) shock and trauma, TBI biomarkers (indicator of biological state or the past or present existence of a particular type of organism or molecule)and screening tools, en route care, permanent pathology caused by mild and moderate TBI and combination drug therapies. Researchers are transitioning selected basic research efforts into applied technology research for promising candidate products. Program announcements are under development for hemorrhage (bleeding) and resuscitation, multimodal neurodiagnostic approaches (combined methods to diagnose neurological conditions), and soft tissue injury and wound healing research.

Radiation health effects and countermeasure research is developing small molecules, protein, and cellular-based strategies for protection and mitigation of radiation-induced tissue injury due to high doses of radiation exposure. Conduct animal studies in mice and non-human primates to characterize promising candidates shown to mitigate or prevent Acute Radiation Syndrome resulting from lethal doses of radiation.

Clinical and rehabilitative medicine is conducting studies in neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury, pain management, regenerative medicine, and/or sensory (hearing and sight) system traumatic injury to

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015

identify and evaluate candidate approaches for incorporation into restoration and rehabilitation strategies and medical products. Specific focus areas include: neuromusculoskeletal injury rehabilitation strategies and devices, prosthetics & orthotics (device/support that corrects/relieves an orthopedic problem), neural interfaces (invasive and non-invasive methods of using the brain for device control), the prevention of heterotopic ossification (growth of bone in abnormal places like soft tissue), and treatment of training injuries to the musculoskeletal system; novel therapeutics and devices for pain management; regenerative medicine-based approaches for limb (extremities) and digit (fingers, thumbs and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, genitourinary restoration and addressing compartment syndrome (muscle, nerve and vascular damage due to swelling post-injury); and restoration and rehabilitation of sensory system injury, including vision, hearing and balance injury and dysfunction. Clinical and rehabilitative medicine is supporting studies started in FY13 focused on evaluating and down-selecting novel diagnostic and treatment strategies in the areas of pain management and sensory system (vision, hearing, and balance) restoration and rehabilitation. Sensory system efforts to be initiated in FY13 were postponed to FY14 due to FY13 sequestration.

FY 2015 Plans:

Military infectious disease research will support multi-year studies in wound infection prevention and management, initiated in FY14, in development of one antibacterial drug class project and one host/pathogen (infectious agent) biomarker project for the detection of bacterial infections in wounds. The second year support will include confirmatory laboratory studies and initial animal studies to demonstrate the drug potency and also to demonstrate the biomarker's accuracy and degree of confidence in identifying pathogens.

Military operational medicine will review project progress and support promising and successful applied research studies initiated in FY13 and FY14 aimed at enhanced nutrition and dietary supplements, Warfighter performance and sustainment in extreme environments (such as extreme heat, cold, or altitude), establishment of return to duty/medical standards criteria, blast injury models and performance standards for protections systems, diagnostics and metrics for hearing loss and protection, alcohol and substance abuse, diagnosis of deployment-related psychological health problems, diagnosis of PTSD, military family and Warfighter resilience, suicide prevention, pulmonary health in the deployed environment, and blast exposure during breaching (process used to force open closed and/or locked doors). The Military Operational Medicine Joint Program will issue program announcements with topics that will be determined by the Military Operational Medicine Joint Program Committee in the areas of physiological health, injury prevention and reduction, psychological health, and environmental health and protection.

Combat casualty care research will advance the studies started in FY14 towards transition to advanced development starting with two products in the treatment of severe hemorrhage, which are on track to move to a full Joint Integrated Product Team by FY15. Other studies moving forward include hemorrhagic (bleeding) shock and trauma, traumatic brain injury (TBI) biomarkers (indicator of biological state or the past or present existence of a particular type of organism or molecule) and screening tools,

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
permanent pathology caused by mild and moderate TBI and combination drug therapies, forward surgical and en route care, and methods to enhance healing of complex injuries of the face, extremities, groin and pelvis. Researchers will transition promising basic research into applied technology research for new candidate products. A program announcement for combat casualty care topics will be issued. Radiation health effects and countermeasure research will continue in the development of small molecules, protein and cellular-based strategies for protection and mitigation of radiation-induced tissue injury due to high doses of radiation exposure. Will conduct animal studies in mice and non-human primates to address research data gaps and to characterize promising candidates shown to mitigate or prevent Acute Radiation Syndrome resulting from lethal doses of radiation. Down select to two candidates for focused studies to mature products in preparation for transition to advance development and an investigational new drug application. Clinical and rehabilitative medicine research will down-select candidate products for transition to technology development in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and/or sensory (hearing and sight) system traumatic injury. Specific focus areas include: neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury rehabilitation strategies and devices, prosthetics (device that replaces a lost body part) and orthotics(devices used to support or supplement a weakened joint or limb), neural interfaces (invasive and non-invasive methods of using the brain and/or nerves in the arms and legs for device control), the prevention and treatment of heterotopic ossification (growth of bone in abnormal places like soft tissue), and treatment of training injuries to the musculoskeletal system; novel therapeutics and devices for pain management; regenerative medicine-based approaches for limb (extremities) and digit (fingers, thumbs and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, repair of skin injury resulting from burns, genitourinary tissue restoration and composite tissue allotransplantation (tissue/organ transplantation between genetically different individuals) and associated immune system modulation technologies; and restoration and rehabilitation of sensory system injury, including vision, hearing and balance injury and dysfunction. Clinical and rehabilitative medicine will continue studies started in FY13 and FY14 focused on evaluating and down-selecting novel diagnostic and treatment strategies in the areas of pain management and sensory system (vision, hearing, and balance) restoration and rehabilitation.			
Accomplishments/Planned Programs Subtotals	30.272	33.192	37.755

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

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. Milestone A packages will be developed to transition promising products to technology development funding.

E. Performance Metrics

Principal Investigators will participate in in-progress reviews, high-level DHP-sponsored review and analysis meetings, submit quarterly and annual status reports to include information on publications, intellectual property, additional funding support, and are subjected to Program Sponsor Representative progress reviews to ensure that milestones are being met and deliverables will be transitioned on schedule. The benchmark performance metric for transition of research conducted with applied research funding will be 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 2015 Defense Health Program			Date: March 2014
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*	Project (Number/Name) 447A / *Military HIV Research Program (Army)*	

COST ($ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
447A: *Military HIV Research Program (Army)*	-	-	8.725	7.175	-	7.175	8.066	8.212	9.289	7.099	Continuing	Continuing

The FY 2015 OCO Request will be submitted at a later date.

A. Mission Description and Budget Item Justification

This project conducts research on the human immunodeficiency virus (HIV), which causes acquired immunodeficiency syndrome (AIDS). 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 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 2013	FY 2014	FY 2015
Title: Military HIV Research Program	-	8.725	7.175
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 2013 Accomplishments: No DHP funding programmed.			
FY 2014 Plans: Program transitions from the Army to DHP. Identify and characterize new populations who are at high risk of being infected with HIV for clinical evaluation of potential new vaccine candidates. Identify and develop new clinical trial sites at overseas locations to test and down-select best candidates for HIV vaccine. Initiate production of additional vaccines for various world-wide HIV subtypes and initiate pre-clinical evaluation in non-human primates.			
FY 2015 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 447A / *Military HIV Research Program (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Will complete production of additional vaccine candidates for various world-wide subtypes. Will develop improved methods to evaluate immune responses to selected HIV vaccine candidates in non-human primates. Will analyze host genetic factors related to HIV acquisition and disease progression in acute HIV infection to inform vaccine development. Will complete down-selection of best candidates for use in Phase 1 safety studies in human volunteers.			
Accomplishments/Planned Programs Subtotals	-	8.725	7.175

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance of the HIV research program will be 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) conducted by USAMRMC Decision Gate process to include Health Affairs representation.