Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program

R-1 ITEM NOMENCLATURE

0130: Defense Health Program

APPROPRIATION/BUDGET ACTIVITY

PE 0602115HP: Applied Biomedical Technology

DATE: March 2013

BA 2: *RDT&E* 

COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
Total Program Element	-	67.160	42.188	46.761	-	46.761	66.699	71.233	75.608	76.969	Continuing	Continuing
200A: Congressional Special Interests	-	34.750	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
306B: Advanced Diagnostics & Therapeutics Research & Development (Air Force)	-	3.377	3.566	3.637	-	3.637	3.710	3.840	3.905	3.975	Continuing	Continuing
372A: GDF Applied Biomedical Technology	-	29.033	38.622	34.148	-	34.148	54.020	58.430	62.579	63.705	Continuing	Continuing
447A: Military HIV Research Program (Army)	-	0.000	0.000	8.976	-	8.976	8.969	8.963	9.124	9.289	Continuing	Continuing

<sup>\*</sup> FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## 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, established for the Defense Health Program Research, Development, Test and Evaluation (RDT&E) funding. Research supported by this program element includes polytrauma and blast injury, rehabilitation, diagnosis and treatment of brain injury, operational health and performance, radiation countermeasures, and psychological health and well-being for military personnel and families.

For the Army Medical Command, beginning in FY14, the military HIV research program funding is transferred from the Army to the Defense Health Program. HIV causes acquired immunodeficiency syndrome (AIDS). 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 future vaccine refinement, and evaluating and preparing overseas sites for future vaccine trials.

PE 0602115HP: Applied Biomedical Technology Defense Health Program

**UNCLASSIFIED** 

Page 1 of 15 R-1 Line #3

<sup>\*\*</sup> The FY 2014 OCO Request will be submitted at a later date

Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program

DATE: March 2013

APPROPRIATION/BUDGET ACTIVITY

0130: Defense Health Program

BA 2: RDT&E

R-1 ITEM NOMENCLATURE

PE 0602115HP: 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, and Peer-Reviewed Hemorrhage (bleeding) Control 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 2012	FY 2013	<b>FY 2014 Base</b>	FY 2014 OCO	FY 2014 Total
Previous President's Budget	66.841	42.188	37.785	-	37.785
Current President's Budget	67.160	42.188	46.761	-	46.761
Total Adjustments	0.319	0.000	8.976	-	8.976
<ul> <li>Congressional General Reductions</li> </ul>	-	-			
<ul> <li>Congressional Directed Reductions</li> </ul>	-	-			
<ul> <li>Congressional Rescissions</li> </ul>	-	-			
<ul> <li>Congressional Adds</li> </ul>	-	-			
<ul> <li>Congressional Directed Transfers</li> </ul>	-	-			
Reprogrammings	-	-			
SBIR/STTR Transfer	0.319	-			
<ul> <li>Military HIV Research Program</li> </ul>	-	-	8.976	-	8.976

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

**Project:** 200A: Congressional Special Interests

Congressional Add: 426A – Traumatic Brain Injury and Psychological Health (TBI/PH) (Army)

Congressional Add: 437A - Peer-Reviewed Hemorrhage Control Research

	FY 2012	FY 2013
PH) (Army)	31.750	-
	3.000	-
Congressional Add Subtotals for Project: 200A	34.750	0.000
Congressional Add Totals for all Projects	34.750	0.000

Congressional Add Totals for all Project

Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Prog	gram	DATE: March 2013
	R-1 ITEM NOMENCLATURE PE 0602115HP: Applied Biomedical Technology	
BA 2: <i>RDT&amp;E</i>	,,	

## **Change Summary Explanation**

FY 2012: Restore FY 2013 President's Budget decrease to Congressional Special Interest from DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (-\$0.869 million) to DHP RDT&E, PE 0602115- Applied Biomedical Technology (+\$0.869 million).

Realignment from DHP RDT&E, PE 0602115-Applied Biomedical Technology (-\$0.550 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$0.550 million).

FY 2013: No Change

FY 2014: Change Proposal increase to DHP RDT&E, PE 0602115-Applied Biomedical Technology (+\$8.976 million) for the Military HIV Research Program (MHRP) from RDT&E, Army, appropriation.

	Exhibit R-2A, RDT&E Project Ju	stification:	: PB 2014 D	Defense Hea	alth Progran	n					<b>DATE:</b> Mai	rch 2013	
APPROPRIATION/BUDGET ACTIVITY 0130: Defense Health Program BA 2: RDT&E				R-1 ITEM NOMENCLATURE PE 0602115HP: Applied Biomedical Technology  PROJECT 200A: Con				ngressional Special Interests					
	COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
	200A: Congressional Special	-	34.750	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## A. Mission Description and Budget Item Justification

For FY12, DHP Congressional Special Interests (CSI) directed funding to stimulate innovative research through a competitive, peer-reviewed research program focused on Peer-Reviewed Traumatic Brain Injury and Psychological Health Research, and Peer-Reviewed Hemorrhage Control Research. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013
Congressional Add: 426A – Traumatic Brain Injury and Psychological Health (TBI/PH) (Army)	31.750	-
FY 2012 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) CSI project 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 applied research, technology development and concept 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, 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; they 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 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 in patients with a history of multiple concussions.		
Congressional Add: 437A - Peer-Reviewed Hemorrhage Control Research	3.000	-

<sup>\*\*\*</sup> The FY 2014 OCO Request will be submitted at a later date

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program	DATE: March 2013	
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT
0130: Defense Health Program	PE 0602115HP: Applied Biomedical	200A: Congressional Special Interests
BA 2: RDT&E	Technology	

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013
FY 2012 Accomplishments: The CSI for Peer-Reviewed Hemorrhage Control Research is intended to seek solutions to uncontrolled bleeding without clotting resulting from severe trauma. Approximately 38% of severe combat trauma patients suffer unexplained heavy and prolonged bleeding after injury which makes hemorrhage control extremely difficult. Applied research efforts seek solutions to develop diagnostics or treatments for this life-threatening condition. Platelets are important in stopping bleeding. Currently, platelets must be administered within 5 days of collection because they must be kept at room temperature. Thus it is impossible to collect platelets in CONUS and ship them to the battlefield. Solutions are being sought to extend this timeline as long as possible, and yet make them quickly useable during a trauma scenario with a minimum of logistic support requirements.		
Congressional Adds Subtotals	34.750	0.000

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

N/A

Remarks

D. Acquisition Strategy

N/A

**E. Performance Metrics** 

N/A

Exhibit R-2A, RDT&E Project Ju	ustification	: PB 2014 C	Defense Hea	ılth Prograr	n					DATE: Ma	rch 2013	
APPROPRIATION/BUDGET ACTIVITY 0130: Defense Health Program BA 2: RDT&E					R-1 ITEM NOMENCLATURE PE 0602115HP: Applied Biomedical Technology				PROJECT 306B: Advanced Diagnostics & Therapeutics Research & Development (Air Force)			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
306B: Advanced Diagnostics & Therapeutics Research & Development (Air Force)	-	3.377	3.566	3.637	-	3.637	3.710	3.840	3.905	3.975	Continuing	Continuing

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

### A. Mission Description and Budget Item Justification

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

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.

Title: Advanced Diagnostics & Therapeutics Research & Development (Air Force)	3.377	3.566	3.637
<b>Description:</b> 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 2012 Accomplishments:  Continued to support regenerative medicine program at Armed Forces Institute of Regenerative Medicine. Completed AF Surgeon General-directed deep-dive on Telecombat as it relates to the health impact on AF operators. Continued nanotechnology research projects at the Massachusetts Institute of Technology. Obtained Institutional Review Board approval for Personalized Medicine/Genomic Medicine project and initiated the associated clinical utility study. Established an advisory panel for personalized medicine/genomic medicine. Supported a continuing forum to educate leaders on futures based thinking; created a learning laboratory for mid-level leadership development, and initiated a strategic roadmap to chart health/healthcare direction. Initiated research on the development of a global events tool to filter, aggregate analyze information from public/Government sources. Analyzed outcomes of symposium on genomics ethical and social policy issues; submitted two associated papers for publication. Awarded intramural project to identify and characterize epigenetic biomarkers of stress caused by high altitude			

PE 0602115HP: Applied Biomedical Technology Defense Health Program

FY 2012 FY 2013 FY 2014

<sup>\*\*\*</sup> The FY 2014 OCO Request will be submitted at a later date

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Progra	m		DATE: March 2013
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	<b>PROJECT</b>	
0130: Defense Health Program	PE 0602115HP: Applied Biomedical	306B: <i>Adva</i>	anced Diagnostics &
BA 2: <i>RDT&amp;E</i>	Technology	Therapeuti	cs Research & Development (Air
		Force)	

, Gree	,		
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014
conditions in a collaborative clinical translational research project in collaboration with the Uniformed Services University of the Healthcare Sciences (USUHS).			
FY 2013 Plans:  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:  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.			

## 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)

PE 0602115HP: *Applied Biomedical Technology* Defense Health Program

**UNCLASSIFIED** 

Page 7 of 15 R-1 Line #3

**Accomplishments/Planned Programs Subtotals** 

3.377

3.566

3.637

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defen	nse Health Program	DATE: March 2013
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT
0130: Defense Health Program	PE 0602115HP: Applied Biomedical	306B: Advanced Diagnostics &
BA 2: RDT&E	Technology	Therapeutics Research & Development (Air
		Force)
E. Performance Metrics		
Individual initiatives are measured through a quarterly annu measured against standardized criteria for cost, schedule a		
breaches in key areas are reviewed and a decision is rende		
•		•

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program									DATE: Mai	rch 2013		
APPROPRIATION/BUDGET ACTIVITY 0130: Defense Health Program BA 2: RDT&E								PROJECT 372A: GDF Applied Biomedical Technology				
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
372A: GDF Applied Biomedical Technology	-	29.033	38.622	34.148	-	34.148	54.020	58.430	62.579	63.705	Continuing	Continuing

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

### A. Mission Description and Budget Item Justification

Accomplishments/Planned Programs (\$ in Millions)

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 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, diagnosis and life support, craniomaxillofacial (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, 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 2012	FY 2013	FY 2014
Title: GDF Applied Biomedical Technology	29.033	38.622	34.148
<b>Description:</b> 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 2012 Accomplishments:  Military infectious diseases research saw significant progress in two platforms for rapid screening of pre-transfused whole blood for pathogens (Task Area: Rapid Screening of Fresh Whole Blood). Down selection will occur in FY14, and if successful, subsequent RFP with 6.4 DHP funds will be announced in FY15. Supported multi-year studies initiated in FY10 and FY11 to transition the most appropriate efforts in development of antibacterial agents for biofilms (a thin layer of microorganisms adhering to the surface of a structure) and multidrug-resistant organisms (MDROs), detection of MDROs, and biomarker and diagnostic assay development to Medical Technology Development.			

PE 0602115HP: Applied Biomedical Technology Defense Health Program

EV 2042 EV 2042 EV 2044

<sup>##</sup> The FY 2014 OCO Request will be submitted at a later date

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense	e Health Program	,	DATE:	March 2013	
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJ	ECT		
0130: Defense Health Program BA 2: RDT&E	PE 0602115HP: Applied Biomedical Technology	372A:	372A: GDF Applied Biomedical Techr		
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
Military operational medicine efforts evaluated models of blast a mechanisms of blast-induced trauma and allow for the develop the effectiveness of pharmacological interventions for treatmen progression and recovery; validated the interventions currently following exposure to toxic substances; characterized abnorma to normal lungs and lung samples from non-deployed personne exposure to adversity (e.g., resilience, recovery, growth, disord between Service member deployment, diagnosis of mental illne violence; and characterized a comprehensive set of PTSD-relar restriction and of juvenile stress as risk factors of PTSD.	ment of optimal protective equipment. Research assessed to of tissue injury and cognitive dysfunction during heat stress employed; investigated candidate biomarkers for lung diserbities in lung tissue samples from deployed personnel compel; investigated what developmental trajectories emerge after) during the deployment cycle; evaluated the causal relaters in active duty Service members, and events of intra-fame	ss ase pared er ionship nily			
Combat casualty care continued to advance successful research biomarkers and screening tools, and combination drug therapie was released and research was initiated in the areas of enroute pathology caused by mild and moderate TBI.	es, to higher categories of funding. A new program announ	cement			
Radiation health effects and countermeasure research studied gastrointestinal tract damage following high dose acute radiation humans that regulates production of platelets by bone marrow) Evaluated the use of Captopril with and without a multipotent production of platelets by bone marrow)	on exposure. Evaluated Alxn4100TPO, a thrombopoietin (panalogue (a similar protein) for treatment of acute radiation	rotein in injury.			
Clinical and rehabilitative medicine performed studies, initiated ossification (HO) (growth of bone in abnormal places like soft ti treadmill-based training for neuromusculoskeletal rehabilitation skin.	ssue) including the development of an animal model of HO	, '			
FY 2013 Plans: Military infectious diseases research is supporting multi-year st agents for biofilms and multidrug-resistant organisms (MDROs) development for down selection and transition of promising effort	), detection of MDROs, and biomarker and diagnostic assa				
Military operational medicine researchers are validating the pre pulmonary samples from deployed Warfighters exposed to pote small airways disease to standardize interpretation of lung biop	entially toxic particulate material; developing a scoring syste				

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense	Health Program		DATE:	March 2013	
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJ	ECT		
0130: Defense Health Program BA 2: RDT&E	PE 0602115HP: Applied Biomedical Technology	372A:	2A: GDF Applied Biomedical Tech		
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
components in post-deployment lung tissue samples compared to social factors and assets predict a resilient trajectory following exputition and dietary supplement benefits to physiological health; relationship between individual factors such as demographics, mand deployment factors on diagnosis of mental illness and intrafsuccessful implementation of future interventions for mental illness relevance for drug treatment development in PTSD that will lead	coposure to adversity during the deployment cycle; evaluate evaluating specific factors that may modify the causal illitary occupational specialties and prior health, family factorially violence; establishing recommendations to enhances and intra-family violence; and identifying specific targe	tors the ts with			
Combat casualty care researchers are continuing studies, initiate TBI biomarkers and screening tools, enroute care, permanent patherapies. Researchers will start applied technology research of Joint Program Committee from a group of products currently in b that will be determined by the Combat Casualty Care Joint Program	athology caused by mild and moderate TBI and combination new products that will be chosen by the Combat Casualt asic research and will issue a program announcement with the combat Casualt asic research and will issue a program announcement with the combat case.	on drug y Care			
Radiation health effects and countermeasure research is address cellular-based strategies for protection and mitigation of radiation. The studies are exploring advances in the development of bioinfold (calculating the absorbed dose) for triage and patient management.	n-induced tissue injury due to high doses of radiation expormatics and physics-based approaches to biodosimetry				
Clinical and rehabilitative medicine is continuing studies in neuro and/or sensory system traumatic injury to identify and evaluate c rehabilitation strategies and medical products. Specific focus are and devices, prosthetics, and the prevention of heterotopic ossifi novel therapeutics and devices for pain management; regeneratic craniomaxillofacial (skull, face and jaw) reconstruction, scarless addressing compartment syndrome (muscle and nerve damage sensory system injury, including vision, hearing and balance injury	andidate approaches for incorporation into restoration an eas include: neuromusculoskeletal injury rehabilitation str cation (growth of bone in abnormal places like soft tissue ve medicine-based approaches for limb and digit salvage wound healing, burn repair, genitourinary restoration and due to swelling post-injury); and restoration and rehabilita	d ategies );			
FY 2014 Plans: Military infectious disease research will continue to support multiagents for biofilms and multidrug-resistant organisms (MDROs), development for down selection and transition of promising effort announcement to solicit novel proposals in the areas of drug disc management, acute respiratory diseases, as well as further strength.	detection of MDROs, and biomarker and diagnostic assa ts to Medical Technology Development. Release of prog covery and development for wound infection prevention a	y am			

PE 0602115HP: *Applied Biomedical Technology* Defense Health Program

UNCLASSIFIED
Page 11 of 15

R-1 Line #3

	UNCLASSIFIED				
Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense He	ealth Program		DATE:	March 2013	
APPROPRIATION/BUDGET ACTIVITY 0130: Defense Health Program BA 2: RDT&E	R-1 ITEM NOMENCLATURE PE 0602115HP: Applied Biomedical Technology		ROJECT '2A: GDF Applied Biomedical Tech		
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
Military operational research will continue studies, initiated in FY12 performance and sustainment in extreme environments (such as ex medical standards criteria, blast injury models and performance state for hearing loss and protection, alcohol and substance abuse, diagratiangosis of PTSD, military family and warfighter resilience, suicide and blast exposure during breaching. The Military Operational Medareas of physiological health, injury prevention and reduction, psychological casualty care research will continue studies, initiated in FY biomarkers and screening tools, enroute care, permanent patholog therapies. Researchers will start applied technology research of new Joint Program Committee from a group of products currently in base that will be determined by the Combat Casualty Care Joint Program Radiation health effects and countermeasure research will continue based strategies for protection and mitigation of radiation-induced the advances in the development of bioinformatics and physics based awill continue to be pursued in support of a comprehensive radiation.  Clinical and rehabilitative medicine will continue studies in neuromal and/or sensory (hearing and sight) system traumatic injury to identification estoration and rehabilitation strategies and medical products. The restoration and rehabilitation strategies and medical products. The prevention of heterotopic ossification treatment of training injuries to the musculoskeletal system; novel the medicine-based approaches for limb and digit salvage, craniomaxil healing, burn repair, genitourinary restoration and addressing compt to swelling post-injury); and restoration and rehabilitation of sensory dysfunction. Clinical and rehabilitative medicine will continue studies novel diagnostic and treatment strategies in the areas of pain manarestoration and rehabilitation.	ktreme heat, cold, or altitude), will establish return to distindards for protections systems, diagnostics and metrinosis of deployment-related psychological health problementation, pulmonary health in the deployed environation. Joint Program will issue program announcement hological health, and environmental health and protect and 13, in hemorrhagic (bleeding) shock and traumy caused by mild and moderate TBI and combination of the products that will be chosen by the Combat Casualic research and will issue a program announcement win Committee.  The in the development of small molecules, protein and consistent injury due to high doses of radiation exposure. It is approaches to biodosimetry for triage and patient man a countermeasures program.  The sculoskeletal injury, pain management, regenerative refusing and evaluate candidate approaches for incorporational interfaces (invasive and non-invasive methods of using on (growth of bone in abnormal places like soft tissue) therapeutics and devices for pain management; regenerational (skull, face and jaw) reconstruction, scarless we cartment syndrome (muscle, nerve and vascular damany system injury, including vision, hearing and balance is started in FY13 focused on evaluating and down-sees and form in the deployed environ description in the deployed environ description de	uty/ cs ems, ment, s in the ion.  a, TBI lrug y Care ith topics  ellular- Research agement  medicine, n jury g , and erative ound ge due njury and lecting			

PE 0602115HP: *Applied Biomedical Technology* Defense Health Program

UNCLASSIFIED

Page 12 of 15 R-1 Line #3

**Accomplishments/Planned Programs Subtotals** 

29.033

38.622

34.148

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program	DATE: March 2013		
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT	
0130: Defense Health Program	PE 0602115HP: Applied Biomedical	372A: <i>GDF</i>	Applied Biomedical Technology
BA 2: RDT&E	Technology		

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

N/A

## **Remarks**

# D. Acquisition Strategy

N/A

## **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, RD1&E Project Justification: PB 2014 Defense Health Program									DAIE: Mar	ch 2013			
APPROPRIATION/BUDGET ACTIVITY					R-1 ITEM NOMENCLATURE PROJ				<b>PROJECT</b>	ROJECT			
0130: Defense Health Program					PE 0602115HP: Applied Biomedical 447A: Mil				447A: Milit	litary HIV Research Program			
BA 2: <i>RDT&amp;E</i>					Technology (Army)								
	COST (\$ in Millions)	All Prior			FY 2014	FY 2014	FY 2014					Cost To	Total
	φ in minions)	Years	FY 2012	FY 2013 <sup>#</sup>	Base	OCO##	Total	FY 2015	FY 2016	FY 2017	FY 2018	Complete	Cost
	447A: Military HIV Research	-	0.000	0.000	8.976	-	8.976	8.969	8.963	9.124	9.289	Continuing	Continuing
	Program (Army)												

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

### A. Mission Description and Budget Item Justification

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.

This project is jointly managed through an Interagency Agreement between USAMRMC and the National Institute of Allergy and Infectious Diseases of the National Institutes of Health. This project contains no duplication of effort within the Military Departments or other government organizations. The cited work is also consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas, and supports the principal area of Military Relevant Infectious Diseases to include HIV.

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014
Title: Military HIV Research Program	0.000	0.000	8.976
<b>Description:</b> 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. <b>FY 2012 Accomplishments:</b> No DHP funding programmed.			
FY 2013 Plans: No DHP funding programmed.			
FY 2014 Plans: Transition 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 at overseas sites and for production of additional vaccines for various HIV subtypes and complete evaluation in non-human primates.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	8.976

PE 0602115HP: *Applied Biomedical Technology* Defense Health Program

Page 14 of 15 R-1 Line #3

<sup>##</sup> The FY 2014 OCO Request will be submitted at a later date

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program	DATE: March 2013		
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	<b>PROJECT</b>	
0130: Defense Health Program	PE 0602115HP: Applied Biomedical	447A: Milit	ary HIV Research Program
BA 2: RDT&E	Technology	(Army)	

## 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 Project Team to include Health Affairs representation.