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 0603115HP *I Medical Technology Development*							
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	713.880	656.441	1,085.108	226.131	-	226.131	231.951	251.289	268.785	264.226	Continuing	Continuing
300A: *CSI - Congressional Special Interests*	540.100	521.585	802.400	-	-	-	-	-	-	-	-	-
238C: *Enroute Care Research & Development (Budgeted) (AF)*	3.261	0.424	4.666	3.394	-	3.394	3.334	4.090	4.479	4.564	Continuing	Continuing
243A: *Medical Development (Lab Support) (Navy)*	33.555	28.413	36.386	34.378	-	34.378	37.580	38.211	40.942	35.462	Continuing	Continuing
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	2.421	0.225	3.694	2.280	-	2.280	3.705	4.697	5.327	6.091	Continuing	Continuing
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	8.005	0.141	4.907	1.983	-	1.983	1.857	2.294	2.699	3.399	Continuing	Continuing
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	14.335	0.393	15.353	12.558	-	12.558	14.173	17.653	19.333	19.700	Continuing	Continuing
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	2.796	0.051	4.769	4.699	-	4.699	4.185	4.159	4.554	4.641	Continuing	Continuing
309A: *Regenerative Medicine (USUHS)*	6.877	-	7.294	9.190	-	9.190	9.489	9.649	9.823	7.945	Continuing	Continuing
373A: *GDF - Medical Technology Development*	48.595	79.544	145.961	113.048	-	113.048	116.775	134.176	149.232	162.193	Continuing	Continuing
378A: *CoE-Breast Cancer Center of Excellence (Army)*	9.722	3.355	10.338	8.664	-	8.664	7.299	5.709	4.068	1.777	Continuing	Continuing
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	8.494	2.931	9.033	7.570	-	7.570	6.377	4.989	3.555	1.552	Continuing	Continuing

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 0603115HP *I Medical Technology Development*							
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	3.584	1.238	3.811	3.594	-	3.594	3.520	3.368	3.214	1.747	Continuing	Continuing
382A: *CoE-Pain Center of Excellence (Army)*	2.715	0.937	2.888	-	-	-	-	-	-	-	Continuing	Continuing
382B: *CoE-Pain Center of Excellence (USUHS)*	0.000	-	-	2.722	-	2.722	2.823	2.871	3.247	2.810	Continuing	Continuing
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	7.164	6.352	8.061	6.907	-	6.907	6.260	5.456	4.628	1.887	Continuing	Continuing
398A: *CoE-Neuroscience Center of Excellence (USUHS)*	1.822	-	1.926	-	-	-	-	-	-	-	-	-
429A: *Hard Body Armor Testing (Army)*	0.813	0.543	-	-	-	-	-	-	-	-	-	-
431A: *Underbody Blast Testing (Army)*	14.544	6.385	11.289	4.818	-	4.818	2.679	1.869	-	-	-	-
448A: *Military HIV Research Program (Army)*	0.000	-	6.912	5.773	-	5.773	6.589	6.701	7.579	5.792	Continuing	Continuing
830A: *Deployed Warfighter Protection (Army)*	5.077	3.924	5.420	4.553	-	4.553	5.306	5.397	6.105	4.666	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 - Medical Technology Development provides funds for promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. Research in this Program Element (PE) is designed to address the following: Secretary of Defense areas of interest 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 and execution is peer-reviewed and fully 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. 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 PE includes polytrauma (multiple traumatic injuries) and blast injury, diagnosis and treatment of brain injury, environmental health and performance, physiological (human mechanical, physical and biochemical functions) and psychological health, injury prevention and reduction, medical simulation and training, health informatics, pain management, regenerative medicine, and rehabilitation of neuro-musculoskeletal injuries and sensory systems. As research efforts mature, the most promising will transition to advanced concept development funding, Program Element 0604110. For knowledge products, successful findings will transition into clinical practice guidelines.

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 0603115HP / *Medical Technology Development*

For the Army Medical Command, the Hard Body Armor project focuses on scientific study and evaluation of injuries related to blunt trauma events on cadavers. Preventing blunt trauma injury is one of the critical components of body armor design.

For the Army Medical Command and the Army Research, Development, and Engineering Command, the Underbody Blast (UBB) Testing medical research project provides funds to establish a scientific and statistical basis for evaluating skeletal injuries to vehicle occupants during ground vehicle UBB events. Areas of interest to the Secretary of Defense are medical research that provides an understanding of the human response and tolerance limits and injury mechanisms needed to accurately predict skeletal injuries to ground combat vehicle occupants caused by UBB events. This enhanced understanding will support the establishment of an improved capability to conduct Title 10 Live Fire Test and Evaluation and to make acquisition decisions.

For the Army Medical Command, beginning in FY14, Military Human Immunodeficiency Virus (HIV) Research Program funding is transferred from the Army to the Defense Health Program. This project funds research to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect military personnel from risks associated with HIV infection.

For the Army Medical Command, the Armed Forces Pest Management Board (AFPMB) Deployed Warfighter Protection project provides for the development of new or improved protection of ground forces from disease-carrying insects.

For the Army Medical Command, four Centers of Excellence (CoE) receive medical technology development funds. The Breast Cancer Center of Excellence (Army) provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. The Gynecologic Center of Excellence (Army) focuses on characterizing the molecular alterations associated with benign and malignant gynecologic disease and facilitates the development of novel early detection, prevention and biologic therapeutics (a medicinal preparation created by a biological process used to treat diseases) for the management of gynecologic disease. The Cardiac Health Center of Excellence (Army) provides evidence-based personalized patient engagement approaches for comprehensive cardiac (pertaining to the heart) event prevention through education, outcomes research and technology tools, as well as molecular research to detect cardiovascular (CV) (pertaining to the heart and blood vessels) disease at an early stage to ultimately discover a signature for CV health, to find new genes that significantly increase risk for heart attack in Service members and other beneficiaries, and identify molecular markers of obesity and weight loss. The Pain Center of Excellence (Army) examines the relationship between acute (rapid onset and/or short course) and chronic (persistent or long-lasting, usually longer than 3 months) pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect this has throughout the continuum to rehabilitation and reintegration. In FY15, the Pain CoE funding line is transferred from Army to USUHS.

In FY13, DHP funded the following Congressional Special Interest (CSI) peer-reviewed directed research: Amyotrophic Lateral Sclerosis (ALS) (degenerative neuronal disorder that causes muscle weakness and atrophy throughout the body), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis (MS) (disease that affects the brain and the spinal cord and causes severe physical and mental complications), Cancer, Lung Cancer, Orthopedic Research, Spinal Cord Research, Vision, Traumatic Brain Injury and Psychological Health (TBI/PH), Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer Research, Joint Warfighter Medical Research, Global HIV/AIDS Prevention, Tuberous Sclerosis Complex (rare multi-system genetic disease that causes growth of non-malignant tumors in the brain and other vital organs), Duchenne Muscular Dystrophy (gene mutation affecting approximately 1 in 3600 boys that causes

muscle degeneration and eventual death), and the Walter Reed National Military Medical Comprehensive Cancer Center. Because of the CSI annual structure, out-year funding is not programmed.

For the Navy Bureau of Medicine and Surgery, this program element includes funds for research management support costs. The Outside Continental US (OCONUS) laboratories conduct focused medical research on vaccine development for Malaria, Diarrhea Diseases, and Dengue Fever. In addition to entomology, HIV studies, surveillance and outbreak response under the Global Emerging Infections Surveillance (GEIS) program and risk assessment studies on a number of other infectious diseases that are present in the geographical regions where the laboratories are located. The CONUS laboratories conduct research on Military Operational Medicine, Combat Casualty Care, Diving and Submarine Medicine, Infectious Diseases, Environmental and Occupational Health, Directed Energy, and Aviation Medicine and Human Performance.

For the Air Force Medical Service (AFMS), funding in this program element supports the Air Force Surgeon General's vision for "Trusted Care Anywhere" through a robust research and development program. Medical development programs are divided into five primary thrust areas: Enroute care, Expeditionary Medicine, Operational Medicine (in-garrison care), Force Health Protection (FHP) (detect, prevent, threats), and Human Performance. Expeditionary Medicine is focused on care on the battlefield and in field hospitals prior to transporting patients out of theater to CONUS, and studies trauma resuscitation, hemorrhage control, and other life-saving interventions to keep critically wounded patients alive in the golden hour and to the next level of care. The AFMS is the only service transporting patients on long aeromedical evacuation missions from theater to Landstuhl and from Landstuhl to CONUS. Therefore, the Enroute Care thrust area studies include patient timing to transport, cabin altitude, noise, vibration, and environmental issues affecting patient physiology on the aircraft, and the Human Performance thrust area compliments Enroute Care through its studies on medic and aircrew performance on long missions, as well as special operations forces performance. Medical development and biomedical technology investments in FHP seek to deliver an improved force health protection capability across the full spectrum of operations with research that prevents injury/illness through improved identification and control of health risks. Under Force Health Protection, sub-project areas include: Directed Energy, Occupational and Environmental Health, and Advanced Diagnostics/Therapeutics. Operational medicine is focused on in garrison care – our next most critical issue post OIF/OEF – and how to care for the whole patient and consideration of comorbidities in treatment of wounded warriors and dependents.

For the Uniformed Services University of the Health Sciences (USUHS), Medical Development programs include the Neuroscience CoE, the Prostate Cancer CoE, and the Center for Neuroscience and Regenerative Medicine. The Neuroscience Center of Excellence (CoE), formerly a Congressional Special Interest program, was chartered in 2002 to conduct basic, clinical and translational research studies of militarily relevant neurological disorders affecting US service members and military medical beneficiaries. The Center's mission is to improve prevention, diagnosis and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions. The Prostate CoE, formerly a Congressional Special Interest program, was chartered in 1992 to conduct basic, clinical and translational research programs to combat diseases of the prostate. The program's mission is fulfilled primarily through its three principal programs- the Clinical Translational Research Center, the Basic Science Research Program and the Tri-Service Multicenter Prostate Cancer Database which encompasses its clinical research work with other participating military medical centers. These affiliated sites contribute data and biospecimens obtained from prostate cancer patients and participate in clinical trials. The Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center.

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 0603115HP / *Medical Technology Development*			
B. Program Change Summary ($ in Millions)	**FY 2013**	**FY 2014**	**FY 2015 Base**	**FY 2015 OCO**	**FY 2015 Total**
Previous President's Budget	239.110	290.852	298.948	-	298.948
Current President's Budget	656.441	1,085.108	226.131	-	226.131
Total Adjustments	417.331	794.256	-72.817	-	-72.817
• Congressional General Reductions	-1.057	-			
• Congressional Directed Reductions	-132.475	-			
• Congressional Rescissions	-	-			
• Congressional Adds	567.355	802.400			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-8.136	-			
• SBIR/STTR Transfer	-8.356	-8.144			
• Reductions related to Departmental Efficiencies - Project 238C	-	-	-1.106	-	-1.106
• Reductions related to Departmental Efficiencies - Project 243A	-	-	-3.820	-	-3.820
• Reductions related to Departmental Efficiencies- Project 284B	-	-	-1.520	-	-1.520
• Reductions related to Departmental Efficiencies - Project 285A	-	-	-1.982	-	-1.982
• Reductions related to Departmental Efficiencies - Project 307B	-	-	-4.090	-	-4.090
• Reductions related to Departmental Efficiencies - Project 308B	-	-	-1.530	-	-1.530
• Realignment MCNoE Research - Project 309A	-	-	1.533	-	1.533
• Reductions related to Departmental Efficiencies - Project 373A	-	-	-48.681	-	-48.681
• Reductions related to Departmental Efficiencies - Project 378A	-	-	-2.166	-	-2.166
• Reductions related to Departmental Efficiencies - Project 379A	-	-	-1.893	-	-1.893
• Reductions related to Departmental Efficiencies - Project 381A	-	-	-0.399	-	-0.399
• Reductions related to Departmental Efficiencies - Project 382A	-	-	-3.025	-	-3.025

• Transfer of Pain Center of Excellence (CoE) to USUHS - Project 382B	-	-	2.722	-	2.722
• Reductions related to Departmental Efficiencies - Project 383A	-	-	-1.727	-	-1.727
• Reductions related to Departmental Efficiencies - Project 398A	-	-	-2.017	-	-2.017
• Reductions related to Departmental Efficiencies - Project 431A	-	-	-0.535	-	-0.535
• Reductions related to Departmental Efficiencies - Project 448A	-	-	-1.443	-	-1.443
• Reductions related to Departmental Efficiencies - Project 830A	-	-	-1.138	-	-1.138

Congressional Add Details ($ in Millions, and Includes General Reductions)	**FY 2013**	**FY 2014**
Project: 300A: *CSI - Congressional Special Interests*		
Congressional Add: *245A - Amyotrophic lateral Sclerosis (ALS) Research*	6.895	7.500
Congressional Add: *293A - Autism Research*	5.516	6.000
Congressional Add: *296A - Bone Marrow Failure Disease Research*	2.942	3.200
Congressional Add: *310A - Ovarian Cancer Research*	18.386	20.000
Congressional Add: *328A - Multiple Sclerosis Research*	4.596	5.000
Congressional Add: *335A - Peer-Reviewed Cancer Research*	13.789	25.000
Congressional Add: *336A - Peer-Reviewed Lung Cancer Research*	9.652	10.500
Congressional Add: *337A - Peer-Reviewed Orthopedic Research*	27.578	30.000
Congressional Add: *338A - Peer-Reviewed Spinal Cord Research*	27.578	30.000
Congressional Add: *339A - Peer-Reviewed Vision Research*	9.193	10.000
Congressional Add: *352A - Traumatic Brain Injury/ Psychological Health Research*	73.241	100.000
Congressional Add: *380A - Peer-Reviewed Breast Cancer Research*	110.330	120.000
Congressional Add: *390A - Peer-Reviewed Prostate Cancer Research*	73.542	80.000
Congressional Add: *392A - Gulf War Illness Peer-Reviewed Research*	18.386	20.000
Congressional Add: *396A - Research in Alcohol and Substance Use Disorders*	3.677	4.000
Congressional Add: *400A - Peer-Reviewed Medical Research*	45.964	200.000

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 0603115HP / *Medical Technology Development*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2013	FY 2014
Congressional Add: *417A - Peer-Reviewed Alzheimer Research*	11.031	12.000
Congressional Add: *439A - Joint Warfighter Medical Research*	34.274	65.000
Congressional Add: *451A - Walter Reed National Military Medical Comprehensive Cancer Center*	9.193	-
Congressional Add: *452A - Peer-Reviewed Reconstructive Transplant Research*	-	15.000
Congressional Add: *453A - Trauma Clinical Research Repository*	-	5.000
Congressional Add: *454A - Orthotics and Prosthetics Outcomes Research*	-	10.000
Congressional Add: *456A - HIV/AIDS Program*	-	7.000
Congressional Add: *540A - Global HIV/AIDS Prevention (Navy)*	7.364	8.000
Congressional Add: *660A - Tuberous Sclerosis Complex (TSC)*	5.516	6.000
Congressional Add: *790A - Duchenne Muscular Dystrophy*	2.942	3.200
Congressional Add Subtotals for Project: 300A	521.585	802.400
Congressional Add Totals for all Projects	521.585	802.400

Change Summary Explanation

FY 2013: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603115-Medical Technology Development (-$8.356 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+$8.356 million).

FY 2013: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0603115-Medical Technology Development (+$567.355 million).

FY 2013: General Congressional Reductions to DHP RDT&E, PE 0603115-Medical Technology Development (-$1.057 million).

FY 2013: Congressional Directed Reductions (Sequestration) to DHP RDT&E, PE 0603115-Medical Technology Development (-$132.475 million).

FY 2013: Below Threshold Reprogramming (BTR) from DHP RDT&E PE, 0603115-Medical Technology Development (-$8.136 million) to DHP RDT&E PE, 0606105-Medical Program-Wide Activities (+$8.136 million).

FY 2014: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0603115-Medical Technology Development (+$802.400 million).

FY2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603115-Medical Technology Development (-$8.144 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+$8.144 million).

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 0603115HP *I Medical Technology Development*

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 0603115-Medical Technology Development (-$77.072 million).

FY2015: Transfer of Pain Center of Excellence (CoE) from Army DHP RDT&E, PE 0603115-Medical Development Technology Development (-$2.722 million) to USUHS DHP RDT&E, PE 0603115-Medical Development Technology Development (+$2.722 million).

FY 2015: Change Proposal to merge USUHS DHP RDT&E, PE 0603115-Medical Development Technology Development (+$1.533 million) Center of Excellence for Neuroscience with Regenerative Medicine.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 300A / *CSI - 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
300A: *CSI - Congressional Special Interests*	540.100	521.585	802.400	-	-	-	-	-	-	-	-	-

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

A. Mission Description and Budget Item Justification

In FY13, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY13 Congressionally-directed research is to stimulate innovative research through a competitive, peer-reviewed research program, and focused medical research at intramural and extramural research sites. Specific peer-reviewed research efforts include the following: Amyotrophic Lateral Sclerosis (ALS) (degenerative neuronal disorder that causes muscle weakness and atrophy throughout the body), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis, Cancer, Lung Cancer, Orthopedic Research, Spinal Cord Research, Vision, Traumatic Brain Injury and Psychological Health (TBI/PH), Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer Research, Joint Warfighter Medical Research, Global HIV/AIDS Prevention, Tuberous Sclerosis Complex (rare multi-system genetic disease that causes growth of non-malignant tumors in the brain and other vital organs), Duchenne Muscular Dystrophy (gene mutation affecting boys that causes muscle degeneration and eventual death), and the Walter Reed National Military Medical Comprehensive Cancer Center. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
Congressional Add: 245A - Amyotrophic lateral Sclerosis (ALS) Research	6.895	7.500
FY 2013 Accomplishments: This Congressional Special Interest initiative was directed toward research on Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's disease. The ALS Research Program was a broadly-competed, peer-reviewed research program. Its goal was to contribute to a cure for ALS by funding innovative preclinical research to develop new treatments for ALS. Two award mechanisms were offered in FY13, the Therapeutic Development Award and the Therapeutic Idea Award. Applications will be received in September 2013, followed by scientific peer review in December 2013, and programmatic review in February 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards.		
FY 2014 Plans: This Congressional Special Interest initiative will provide funds for research in Amyotrophic Lateral Sclerosis (ALS).		
Congressional Add: 293A - Autism Research	5.516	6.000
FY 2013 Accomplishments: This Congressional Special Interest research initiative for Autism Research sought to improve treatment outcomes of Autism Spectrum Disorder (ASD), lead to a better understanding of ASD, and integrate basic science and clinical observations by promoting innovative research. The Autism		

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
Research Program has funded research at universities, hospitals, nonprofit and for-profit institutions, as well as private industry. Two award mechanisms were offered in FY13, the Pilot Award and the Idea Development Award. Applications will be received in October 2013, scientific peer review is planned for December 2013, and programmatic review will take place in February 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest research initiative is for Autism Research.		
Congressional Add: 296A - Bone Marrow Failure Disease Research	2.942	3.200
FY 2013 Accomplishments: This Congressional Special Interest initiative funded research for bone marrow failure diseases. The mission of the program is to sponsor innovative research that will advance the understanding of inherited and acquired bone marrow failure diseases, and to improve the health and life of individuals living with these diseases, with the ultimate goal of prevention and/or cure. This effort has solicited research proposals focused on bone marrow failure syndromes and their long-term effects from the basic science and clinical research sectors. In FY13, applications will be accepted through one funding opportunity, the Idea Development Award. Application receipt will be September 2013 with scientific peer review scheduled in November 2013, followed by programmatic review planned for January 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest initiative will fund research for bone marrow failure diseases.		
Congressional Add: 310A - Ovarian Cancer Research	18.386	20.000
FY 2013 Accomplishments: This Congressional Special Interest initiative funds research for Ovarian Cancer. The overall goal of the program was to eliminate ovarian cancer by supporting high-impact, innovative research. In striving to achieve this goal, the FY13 Ovarian Cancer Research Program was supporting innovative ideas that will provide new paradigms, leveraging critical resources, facilitating synergistic, multidisciplinary partnerships, and cultivating the next generation of investigators in ovarian cancer. Five award mechanisms were offered: Ovarian Cancer Academy Award, Pilot Award, Teal Innovator Award, Resource Development Award, and Clinical Translational Leverage Award. Applications are due in August/September 2013; scientific peer review is scheduled for September/October 2013 with programmatic review scheduled for December 2013. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest initiative will fund research in Ovarian Cancer.		
Congressional Add: 328A - Multiple Sclerosis Research	4.596	5.000

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
FY 2013 Accomplishments: This Congressional Special Interest initiative funded research for Multiple Sclerosis (MS). The mission of the program was to support pioneering concepts and high-impact research relevant to the etiology (study of the causes of the disease), pathogenesis (mechanisms that occur during disease development), assessment and treatment of MS with the vision of preventing the occurrence, curing, reversing or slowing the progression, and lessening the personal and societal impact of MS. This effort solicits research applications from the basic science and clinical research sectors. Applications for one funding opportunity will be accepted, the Idea Development Award. Applications receipt is due in September 2013 followed by scientific peer review in early November 2013. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest initiative will fund research in Multiple Sclerosis (MS).		
Congressional Add: 335A - Peer-Reviewed Cancer Research	13.789	25.000
FY 2013 Accomplishments: This Congressional Special Interest research initiative is for the study of cancers designated by Congress. The goal of the Peer-Reviewed Cancer Research Program is to improve the quality of life by significantly decreasing the impact of cancer on service members, their families, and the American public. The funds appropriated by Congress are directed for research in the following areas: blood cancers, colorectal cancer, genetic cancer research, kidney cancer, Listeria vaccine (bacterial-based vaccine) for cancer, melanoma and other skin cancers, mesothelioma (rare form of cancer developed from the protective lining that cover many of the internal organs of the body caused by exposure to asbestos), neuroblastoma (extracraneal solid cancer), pancreatic cancer, and pediatric brain tumors. Two award mechanisms to support these topic areas were released: the Career Development Award and the Idea Award with Special Focus. Applications receipt was October 2013, with a scientific peer review in December 2013, followed by a programmatic review in February 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest research initiative is for the study of cancers impacting service members, their families, and the American public.		
Congressional Add: 336A - Peer-Reviewed Lung Cancer Research	9.652	10.500
FY 2013 Accomplishments: This Congressional Special Interest initiative funds research in Lung Cancer. The vision of the Peer-Reviewed Lung Cancer Research Program is to eradicate deaths from lung cancer to better the health and welfare of the military and the American public. As such, the Lung Cancer Research Program (LCRP) will support and integrate research from multiple disciplines for risk assessment, early detection, diagnosis, prevention, and treatment for the control and cure of lung cancer. To support this vision for		

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
FY13, four award mechanisms were offered in 2013: the Career Development Award, the Clinical Exploration Award, the Idea Development Award, and the Concept Award. Applications were due in July/October 2013. Scientific peer review will be conducted in October/December 2013, and programmatic review for funding recommendations will be made in January 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest initiative will fund research in Lung Cancer.		
Congressional Add: 337A - Peer-Reviewed Orthopedic Research ***FY 2013 Accomplishments:*** This Congressional Special Interest research initiative supports orthopedic research that will advance optimal treatment and rehabilitation from musculoskeletal skin, muscles, bones and bone marrow injuries sustained during combat or combat-related activities. The effort solicited innovative, high-impact and clinically-relevant research, with a focus on collaborations between military and non-military researchers and clinicians. Four award mechanisms were offered in FY13: Clinical Trial, Clinical Trial Development, Translational Research, and Idea Development Awards. Pre-applications were due in April 2013, applications were due in July 2013, scientific peer review took place in September 2013, and programmatic review for funding recommendations was held in November 2013. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest research initiative will support orthopedic research.	27.578	30.000
Congressional Add: 338A - Peer-Reviewed Spinal Cord Research ***FY 2013 Accomplishments:*** This Congressional Special Interest research initiative was to support Spinal Cord Injury (SCI) research. Within this context, this initiative focuses its funding on innovative projects that have the potential to make a significant impact on the health and well-being of military service members, Veterans, and other individuals living with SCI. This research effort is offering four award mechanisms in FY13: Clinical Trial, Investigator-Initiated Research, Qualitative Research and Translational Research Awards. Pre-applications were due in June 2013, applications were due in October 2013, scientific peer review will take place in December 2013, and programmatic review for funding recommendations will be held in February 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest research initiative will support Spinal Cord Injury (SCI) research.	27.578	30.000
Congressional Add: 339A - Peer-Reviewed Vision Research	9.193	10.000

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
FY 2013 Accomplishments: This Congressional Special Interest research effort for Peer-Reviewed Vision Research targets the causes, effects and treatments of eye damage, visual deficits due to traumatic brain injury (TBI) and diseases that, despite their different pathogenesis (mechanisms that occur during disease development), all have a common end result: degeneration of the critical components of the eye and impairment or loss of vision. The results of this research are intended to be used for restoration and maintaining of visual function to ensure and sustain combat readiness. Basic, translational (conversion of findings in basic science to practical applications) and clinical research efforts are sought to ensure that results of scientific research will be used to directly benefit the lives of military, veteran and civilian populations. Critical areas of research include advances and improvements in: vision rehabilitation strategies and quality of life measures, vision restoration, mitigation and treatment of traumatic injuries, treatment for war-related injuries and diseases to ocular structures and the visual system, treatment of visual dysfunction (abnormal functioning pertaining to the eyes) associated with traumatic brain injury (TBI), ocular and visual systems diagnostic capabilities and assessment strategies, and Warfighter vision readiness and enhancement related to refractive surgery. To meet the goals of the program, two award mechanisms support vision research, the Translational Research Award and the Hypothesis Development Award. The Hypothesis Development Awards will have a ceiling not to exceed $250K and a period of performance up to two years. The Translational Research Awards will have a ceiling not to exceed $1.0M and a period of performance up to three years. Pre-applications were due in November 2013, applications are due in February 2014, scientific peer review will take place in March 2014, and programmatic review for funding recommendations will be held in May 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest research effort is for Peer-Reviewed Vision Research.		
Congressional Add: 352A - Traumatic Brain Injury/ Psychological Health Research	73.241	100.000
FY 2013 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest 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 basic research, applied research, technology development and advanced concept development efforts. A key priority of the TBI/PH research program was to complement ongoing Department of Defense (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		

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 300A / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
area of TBI, researchers continued clinical trials to treat mild TBI with an oral drug, a trial using diffusion tensor imaging (method for diagnosing cerebral blood supply restriction known as ischemia) to diagnose mild TBI in service members, and a trial performed in partnership with the NIH looking for better ways to image TBI. Proposals were received for advanced neurotrauma (nerve injury) imaging techniques and for a new VA/DoD, multi-university, trauma consortium to discover mechanisms of treatment and the long-term effects of TBI and its relationship to chronic traumatic encephalopathy (CTE) (progressive degenerative disease, which can only be definitively diagnosed postmortem in individuals with a history of multiple concussions and other forms of head injury). Proposals were also received to conduct applied research to address pain and sensory deficits (vision/hearing and balance) associated with TBI. In the area of psychological health, researchers performed investigations to assess the risk of psychological health problems in children of service members; understand how the deployment cycle affects marriage quality and stability; workplace violence in the military; 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 (TBI/PH) research.		
Congressional Add: 380A - Peer-Reviewed Breast Cancer Research	110.330	120.000
FY 2013 Accomplishments: This Congressional Special Interest research initiative was for studying Breast Cancer. The Breast Cancer Research Program (BCRP) challenged the scientific community to design research that addresses the urgency of ending breast cancer. Applications were either required or encouraged to address at least one of eight overarching challenges, which are focused on metastasis (spread of a cancer from one organ or part to another non-adjacent organ or part), primary prevention, over-diagnosis and overtreatment, safe and effective interventions, risk factors, and/or recurrence. To support the vision of ending breast cancer, five award mechanisms were developed to support meritorious breast cancer research: Breakthrough Award, Era of Hope Scholar Award, Innovator Award, Idea Expansion Award, and Postdoctoral Fellowship Award. The Breakthrough Award accepted applications under four funding levels, depending on the scope of the research project, which could range from initial proof-of-concept to clinical trials. The Breakthrough and Postdoctoral Fellowship Awards were offered twice during this fiscal year. Application submission deadlines were in July and September 2013 and in January 2014. Scientific peer review will be completed in August and November 2013 and in March 2014, and funding recommendations will be made at programmatic reviews in October		

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
2013, January 2014, February 2014, and May 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest research initiative is for studying Breast Cancer.		
Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research	73.542	80.000
FY 2013 Accomplishments: This Congressional Special Interest research was to study Prostate Cancer. The vision for this effort was to conquer prostate cancer by funding research to eliminate death from prostate cancer and enhance the well-being of men experiencing the impact of the disease. To address the most critical current needs in prostate cancer research and clinical care, the Prostate Cancer Research Program (PCRP) developed three overarching challenges to be addressed by the research community: (1) develop better tools to detect clinically relevant disease in asymptomatic men, (2) distinguish aggressive from indolent (slow to develop) disease in men newly diagnosed with prostate cancer, and (3) develop effective treatments and address mechanisms of resistance for men with high risk of metastatic prostate cancer. In addition, research projects were solicited in the areas of biomarker development, genetics, imaging, mechanisms of resistance, survivorship and palliative care (alleviating pain and symptoms without eliminating the cause), therapy, and tumor and microenvironment biology. To meet these goals for FY13, thirteen award mechanisms were developed to support significant prostate cancer research. These included: Biomarker Development Award, Clinical Consortium Award, Collaborative Undergraduate HBCU Student Summer Training Program Award, Exploration-Hypothesis Development Award, Health Disparity Research Award, Idea Development Award, Laboratory-Clinical Transition Award, Physician Research Training Award, Population Science Impact Award, Postdoctoral Training Award, Prostate Cancer Pathology Resource Network Award, Synergistic Idea Development Award, and Transformative Impact Award. Application submission deadlines occurred in July-October 2013, scientific peer review will occur in August-December 2013, and programmatic review and funding recommendations will occur in February-March 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest research is to study Prostate Cancer.		
Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research	18.386	20.000
FY 2013 Accomplishments: This Congressional Special Interest research initiative was for Gulf War Illness Research. The program's vision of improving the health and lives of veterans who have the complex symptoms known as Gulf War Illness is being addressed through the funding of innovative research to identify effective treatments, to improve its definition and diagnosis, and to better understand its pathobiology (study of structural and functional manifestations of a disease with emphasis on the biological aspects) and symptoms. Applications		

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
were accepted for FY13 through four award mechanisms: the Clinical Trial Award, Clinical Trial Development Award, Innovative Treatment Evaluation Award, and Investigator-Initiated Research Award. Applications will be received in September 2013, scientific peer review will be conducted in December 2013, and funding recommendations will be made at programmatic review in February 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest research initiative is for Gulf War Illness Research.		
Congressional Add: 396A - Research in Alcohol and Substance Use Disorders	3.677	4.000
FY 2013 Accomplishments: This Congressional Special Interest research effort on Research in Alcohol and Substance Use Disorders is a competitive program to create translational research addressing alcohol and substance abuse issues. The goal of this project was to develop new treatments for those struggling with alcohol and substance abuse who also suffer from post-traumatic stress disorder (PTSD) and/or traumatic brain injury (TBI). This comes at a crucial time as alcohol and substance abuse continues to rise among service members. Proposals have been received and selected. Animal models are being developed to look at binge drinking and PTSD, along with therapeutic approaches for substance abuse treatment that can reduce binge drinking and may attenuate PTSD symptoms. Primary outcomes are showing positive trends to reduce alcohol consumption, craving for alcohol and PTSD symptoms. Six proof of principle projects were awarded in September 2013. Studies include PTSD and protecting degeneration of the nervous system against alcohol toxic effects on the nerves in order to determine the pathophysiologic significance (functional changes associated with disease or injury) following traumatic stress. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest research effort is for Research in Alcohol and Substance Use Disorders.		
Congressional Add: 400A - Peer-Reviewed Medical Research	45.964	200.000
FY 2013 Accomplishments: This Congressional Special Interest initiative addressed peer-reviewed medical research. The vision of the program was to identify and fund the best medical research to protect and support Warfighters, Veterans, and other beneficiaries and to eradicate diseases that impact these populations. Research proposals submitted to the FY13 program must focus on at least one of the 24 Congressionally-directed topics. These topic areas are: chronic kidney disease, chronic migraine and post-traumatic headaches, composite tissue transplantation, dengue (a severe debilitating disease caused by a virus and transmitted by a mosquito), dystonia (a neurological movement disorder), DNA vaccine technology for post exposure prophylaxis (a treatment to prevent or stop disease from spreading), epilepsy, food allergies, fragile X syndrome (the most widespread single-gene cause of autism and inherited cause of mental retardation among boys), hantavirus,		

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
hereditary angioedema (genetic condition characterized by swelling of the hands, feet, face, abdomen and airway), inflammatory bowel disease, interstitial cystitis (painful bladder syndrome), leishmaniasis, lupus, malaria, nanomedicine for drug delivery science, pancreatitis (inflammation of the pancreas), polycystic kidney disease (a genetic condition that causes fluid-filled cysts to form in the kidney, and the fourth leading cause of kidney failure), post-traumatic osteoarthritis, pulmonary hypertension, rheumatoid arthritis, scleroderma (buildup of scar-like tissue in the skin), and tinnitus. Four funding opportunities have been offered for FY13: the Investigator-Initiated Research Award, Technology/Therapeutic Development Award, Discovery Award, and Clinical Trial Award mechanisms. Application receipt occurred in August 2013 for the Discovery Award and October 2013 for the remaining mechanisms. Scientific peer review was conducted in September 2013 for the Discovery Award, and will be held in -December 2013 for the other three mechanisms. Funding recommendations will be made during programmatic review in February 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest initiative is for Peer-Reviewed Medical Research.		
Congressional Add: 417A - Peer-Reviewed Alzheimer Research	11.031	12.000
FY 2013 Accomplishments: The goal of the Militarily Relevant Peer-Reviewed Alzheimer's (MRPRA) Congressional Special Interest Research Program was to gain an understanding of the genesis of Traumatic Brain Injury (TBI)-associated neurodegenerative disease. Equally important, the program also sought to invest in new strategies dedicated to improving the quality of life for those affected by the similar symptoms of TBI and/or Alzheimer's disease. The MRPRA employs a two-tiered process of scientific and programmatic review. The programmatic review was completed by the MRPRA's Program Steering Committee, comprised of governmental, military, and not-for-profit experts. Fifteen projects were funded with FY12 dollars, including the second phase of the Vietnam Veterans Alzheimer's Disease Neuroimaging Initiative (VVADNI) study. The FY13 funding cycle is halfway completed. Three FY13 award mechanisms were made available: the Convergence Science Research Award, the Quality of Life Research Award and the Military Risk Factors Research Award. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest research program is to study Alzheimer's disease.		
Congressional Add: 439A - Joint Warfighter Medical Research	34.274	65.000
FY 2013 Accomplishments: The Joint Warfighter Medical Research Program (JWMRP) is intended to provide continuing support for promising previously funded Congressional Special Interest projects. The focus is to augment and accelerate high priority DoD and Service medical requirements that are close to achieving their objectives and yielding a benefit to military medicine. Project funding is divided into technology		

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
development and engineering and manufacturing development efforts. The JWMRP directly supports military medical research in military infectious diseases, combat casualty care, military operational medicine, medical simulation and training and health information sciences, and clinical and rehabilitative medicine to include pain management, regenerative medicine, and neuromusculoskeletal and sensory system (hearing and sight) rehabilitation and restoration. Through an iterative process of recommendations, prior year CSI-funded projects were nominated for consideration by the Services, Joint Program Committee Chairs, and execution management activities. Those projects deemed by the Joint Program Committees to have the highest priority to fill critical research or materiel gaps and those projects close to developing a product were invited to submit a full proposal for the next level of effort. A technical review of the full proposals was completed. A Programmatic Review Board recommended 17 projects in the technology development area and 7 projects in the engineering and manufacturing development area for funding. Sequestration reductions will impact the number of awards. The office of the Assistant Secretary of Defense – Health Affairs approved the recommended funding prioritization list. Projects selected for funding are in the initial stages of the contracting process. Most of the awards will be complete by the end of the third quarter of FY14. ***FY 2014 Plans:*** This Congressional Special Interest project will support the Joint Warfighter Medical Research Program (JWMRP).		
Congressional Add: 451A - Walter Reed National Military Medical Comprehensive Cancer Center	9.193	-
FY 2013 Accomplishments: This Congressional Special Interest initiative was to establish a national coordinating cancer center for the cancer centers of excellence. Work is to be conducted at the Walter Reed National Military Medical Center (WRNMMC), and executed by the Joint Task Force National Capital Region Medical Center (JTF CAPMED). The research aims of this propram are directed to the development of evidence-based best practices applicable to most of the MHS. This program will lead to a decrease in the morbidity and mortality of cancer through the integration of basic and translational research discovery, technological advances, clinical trials, aggressive prevention programs and the application of more effective treatments and creation of enhanced clinical and support services. The findings of the studies will provide templates for optimal cancer care, treatment, and support services from the time of detection through the curative stages and beyond into survivorship. Because the Murtha Cancer Center has been designated by the DoD MHS Centers of Excellence Oversight Board as the sole DoD Cancer Center of Excellence, the results of these studies will benefit the total MHS. Three research areas are included: Military Population Sciences and Epidemiology, Biorepository and Research Data Management, and Evidence-based Models for Cancer Management and Care in MTFs. Applications have been received. Scientific peer review will be conducted in		

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
September/October 2013 with programmatic review scheduled for December 2013. Award(s) will be made no later than September 2014.		
Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research ***FY 2013 Accomplishments:*** None. ***FY 2014 Plans:*** This Congressional Special Interest research initiative is for Reconstructive Transplant Research.	-	15.000
Congressional Add: 453A - Trauma Clinical Research Repository ***FY 2013 Accomplishments:*** None. ***FY 2014 Plans:*** This Congressional Special Interest research initiative will study the development of a Trauma Clinical Research Repository.	-	5.000
Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research ***FY 2013 Accomplishments:*** None. ***FY 2014 Plans:*** This Congressional Special Interest research initiative will provide for Orthotics and Prosthetics Outcomes Research.	-	10.000
Congressional Add: 456A - HIV/AIDS Program ***FY 2013 Accomplishments:*** None. ***FY 2014 Plans:*** This Congressional Special Interest research initiative will provide for HIV/AIDS research.	-	7.000
Congressional Add: 540A - Global HIV/AIDS Prevention (Navy) ***FY 2013 Accomplishments:*** Program emphasis was placed on (1) building a national research infrastructure by funding large, multidisciplinary program projects focused on detection; (2) encouraging innovative approaches to research by funding new ideas and technology with or without supporting preliminary data; and (3) recruiting new, independent investigators for careers in research, as well as more senior investigators new to the research field. The strategy for the FY13 Congressionally directed research identified above was to stimulate innovative research through a competitive, peer reviewed research program, as well as focused medical research at intramural and extramural research sites. Specific research efforts included HIV/AIDS. The HIV/AIDS prevention program conducted on-site visits to determine eligible areas for technical assistance and resource support, and provided support to defense forces in the following areas: (1) HIV prevention, which includes training of medical personnel and peer educators, education of military members, provision of condoms and other	7.364	8.000

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
prevention materials, provision of educational materials such as brochures, posters, and booklets; (2) care for HIV-infected individuals and their families to include provision of electronic medical record programs, medications to treat HIV-related issues, physician education, and clinic infrastructure support; (3) treatment services including provision of laboratory services such as HIV test kits, and other laboratory equipment; and (4) Strategic Information including systems to collect information on the effectiveness of HIV treatment and prevention programs and generate databases of such information to guide treatment and prevention programs. The HIV/AIDS Prevention Program provided technical assistance and resource support for 25 foreign defense forces in FY13. Accomplishments included over 35,290 individuals that received testing and counseling services for HIV and received their test results, 34,104 military members and their dependents targeted with HIV prevention interventions, more than 920 health care workers successfully completing an in-service training program, and 3,177 pregnant women knew their HIV status based on testing and counseling services provided to them. Because of the CSI annual structure, out-year funding is not programmed. ***FY 2014 Plans:*** This Congressional Special Interest project will support Global HIV/AIDS Prevention research.		
Congressional Add: 660A - Tuberous Sclerosis Complex (TSC) ***FY 2013 Accomplishments:*** The Congressional Special Interest research initiative for Tuberous Sclerosis Complex (TSC) (rare multi-system genetic disease that causes growth of non-malignant tumors in the brain and other vital organs) was promoting innovative research focused on decreasing the clinical impact of TSC. Within this context, this initiative was encouraging applications that address a number of vital areas of emphasis. This research effort was offering three award mechanisms to support TSC research: Idea Development, Exploration-Hypothesis Development, and Pilot Clinical Trial Awards. Applications were due July 2013, scientific peer review was conducted in August 2013, and funding recommendations will be made at programmatic review in December 2013. Award(s) will be will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** The Congressional Special Interest research initiative is for Tuberous Sclerosis Complex (TSC) research.	5.516	6.000
Congressional Add: 790A - Duchenne Muscular Dystrophy ***FY 2013 Accomplishments:*** This Congressional Special Interest initiative was for research focused on Duchenne Muscular Dystrophy (DMD) (gene mutation affecting approximately 1 in 3600 boys that causes muscle degeneration and eventual death). The vision for this effort was to extend and improve the function, quality of life, and lifespan for all individuals diagnosed with DMD by supporting research to better inform	2.942	3.200

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014
the development of drugs, devices, and other interventions and promote their effective clinical testing. To support this vision for FY13, one award mechanism was offered in 2013, the Investigator-Initiated Research Award. Applications were due in November 2013, scientific peer review will take place in January 2014, and programmatic review will be held in March 2014. Award(s) will be made by September 2014. Sequestration reductions will impact the number of awards. ***FY 2014 Plans:*** This Congressional Special Interest initiative is for research focused on Duchenne Muscular Dystrophy (DMD).		
Congressional Adds Subtotals	521.585	802.400

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Research proposals will be solicited by program announcements resulting in grants, contracts, or other transactions.

E. Performance Metrics

N/A

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 238C / *Enroute Care Research & Development (Budgeted) (AF)*	

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
238C: *Enroute Care Research & Development (Budgeted) (AF)*	3.261	0.424	4.666	3.394	-	3.394	3.334	4.090	4.479	4.564	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Enroute Care Research & Development (Budgeted) (AF)	0.424	4.666	3.394

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

FY 2013 Accomplishments:
Completed Air Worthiness certification for simulator mannequin and initiated use on Aeromedical Evacuation (AE) and Critical Care Transport Team (CCATT) training flights – transitioned to the CCATT Pilot Unit. Continued research to enhance the care of acutely injured AE trauma patients though projects assessing closed loop technology for autonomous control of oxygenation and ventilation. Completed and archived miniaturized Extra Corporal Membrane Oxygenation (ECMO) device bovine study. Analyzed initial results of research assessing the clinical effect of prolonged hypobaria during AE on Traumatic Brain Injury (TBI), how AE affects blood volume responsiveness, pain assessment during AE, and factors impacting patient safety during AE. Began

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 238C / *Enroute Care Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
assessing how the transport of psychiatric patients impacts AE crew protocols. Began research for identifying optimal time to transport patients to ensure best outcomes. Began investigations into advanced development options for AE material solutions: began testing for a portable electrical power source; began development of a negative pressure multi-channel negative pressure wound therapy device; awarded and initiated automation of the CCATT patient record (Form 3899L) onto a widely-accepted portable physiologic monitoring device; and supported Air Mobility Command (AMC) in prototype development for a replacement aircraft patient loading system. Spear-headed DoD Information Assurance Certification and Accreditation Program (DIACAP) for telemedicine capability of a physiologic monitoring device in support of AMC requirements, which will allow for transmission of aeromedical electronic medical information across DoD information platforms. Presented research findings in peer-reviewed journals and at national meetings. ***FY 2014 Plans:*** Finalize FDA requirements and plan for transition of the miniaturized ECMO device to AMC for AE and CCATT use. Make recommendations regarding way-ahead on closed loop ventilation and oxygenation. Complete research assessing the clinical effect of prolonged hypobaria during AE, how AE affects blood volume responsiveness, pain assessment during AE, and factors impacting patient safety during AE. Apply the results of the effectiveness of life saving interventions study to modifying clinical practice guidelines. Identify FDA requirement and transition dates for AE material solutions. ***FY 2015 Plans:*** Plan and test for transition of miniaturized Extra Corporal Membrane Oxygenation device to Air Mobility Command (AMC) for Aeromedical Evacuation (AE) and Combat Casualty Air Transport Team (CCATT) and lung team use on long flight missions. Monitor technology readiness level of closed loop ventilation and oxygenation. Analyze final results of research assessing the clinical effect of prolonged hypobaria during AE, how AE affects blood volume responsiveness, improving pain management during AE, and factors impacting patient safety during AE, and determine translational elements of completed research or need for further studies. Complete and transition automated CCATT patient record and multi-channel negative pressure wound therapy device to acquisition process. Analyze results of cabin altitude restriction retrospective study, which should lead to better evidence-based decision-making for when to fly low. Continue swine study to investigate post AE effects on coagulation and inflammation. Continue investigating new research and development requirements based on results of prior studies and warfighter gap analyses.			
Accomplishments/Planned Programs Subtotals	0.424	4.666	3.394

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program			Date: March 2014
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C. Other Program Funding Summary ($ in Millions)

Line Item	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
• BA-1, PE 0807714HP: *Other Consolidated Health Support*	12.669	13.049	13.441	-	13.441	13.844	14.259	14.655	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinatinons 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 0603115HP / *Medical Technology Development*	Project (Number/Name) 243A / *Medical Development (Lab Support) (Navy)*	

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
243A: *Medical Development (Lab Support) (Navy)*	33.555	28.413	36.386	34.378	-	34.378	37.580	38.211	40.942	35.462	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Medical Development (Lab Support) (Navy)	28.413	36.386	34.378
Description: RDT&E funds for operating and miscellaneous support costs at RDT&E laboratories, including facility, equipment and civilian personnel costs that are not directly chargeable to RDT&E projects. Excludes military manpower and related costs, non-RDT&E base operating costs, and military construction costs, which are included in other appropriate programs.			
FY 2013 Accomplishments: Provided funding for operating and miscellaneous support costs to eight BUMED medical research laboratories across 15 product lines that protect, treat, enhance, and rehabilitate the Warfighter. Operating support funding enabled research staff at the eight labs to achieve high levels of scientific productivity to include: 390 distinct science work units; 164 publications; 301 professional science presentations; 24 formal technical reports; and 31 patent applications.			
FY 2014 Plans: Continue to provide operating and miscellaneous support costs at BUMED research laboratories. Continue to provide support for technologically advanced cutting edge research equipment for research and data acquisition, automated sampling and real time statistical analysis of biomedical research data utilizing data information systems integral with new equipment. Continue to provide replacement of obsolete general purpose research equipment.			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 243A / *Medical Development (Lab Support) (Navy)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Additional Funding received will be used for 64 administrative civilian FTE's that had to be reprogrammed from the overhead account, due to new financial model. Funding will also be used for existing government inherent civilian vacancies that are not in the current manpower controls. ***FY 2015 Plans:*** Provide operating support for eight medical RDT&E labs across 15 product lines to develop products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter, and enable the labs to meet or exceed science performance metric objectives.			
Accomplishments/Planned Programs Subtotals	28.413	36.386	34.378

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metrics include timely and proportionate distribution of funds to labs and product lines to optimize resource utilization in the development and evaluation of products that protect, treat, rehabilitate and enhance the performance of the Warfighter.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 284B / *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	

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
284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*	2.421	0.225	3.694	2.280	-	2.280	3.705	4.697	5.327	6.091	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

Human Performance (Human Physiology, Evaluation & Optimization) Research & Development (Air Force): This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work includes efforts to adapt, survive and thrive in extreme environments. It also addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to operational and environmental challenges to performance.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)	0.225	3.694	2.280

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

FY 2013 Accomplishments:

Achieved initial operational capability of the Operationally Based Vision Assessment (OBVA) project and transitioned it to sustainment. High altitude/U-2 pilot MRI imaging and preliminary comparison to control groups which has supported operational changes. It has also identified a second cohort that has an abnormal level of brain white matter hyper densities, which may be indicative of mild Traumatic Brain Injury (TBI). Began studies of the effects of Modafinil when used in combination with over-the-counter stimulants. A broad study was initiated to monitor the ability to reduce injury rates and effects, both short and long term, through changes in physical training programs for battlefield airman. Mountain acclimatization study recruited subjects and began

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 284B / *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
setup of equipment. A study on risk and protective factors (including their family support) and social-occupational impairment among AF Special Operations Forces was initiated. ***FY 2014 Plans:*** Complete high altitude/U-2 pilot imaging and comparison baseline studies. Complete mountain altitude acclimatization research. Complete the study on risk and protective factors and social-occupational impairment among AF Special Operations Forces personnel. Pursue human systems integration studies. Assess fatigue management using non-visual light stimulation. Expand ongoing studies on understanding hypoxia, focusing on previously unidentified latent effects. ***FY 2015 Plans:*** Complete non-visual light stimulation as a countermeasure for fatigue study. Conclude efforts identifying the effects of combining over-the-counter stimulants with Modafinil, which may stimulate the need for further research. Apply results from high altitude and hypoxia studies to refine this line of research and potentially spur operational changes. Implement plans to pursue human systems integration studies, focusing on identified gaps.			
Accomplishments/Planned Programs Subtotals	0.225	3.694	2.280

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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

D. Acquisition Strategy

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinatinons 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 0603115HP / *Medical Technology Development*	Project (Number/Name) 285A / *Operational Medicine Research & Development (Budgeted) (AF)*	

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
285A: *Operational Medicine Research & Development (Budgeted) (AF)*	8.005	0.141	4.907	1.983	-	1.983	1.857	2.294	2.699	3.399	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Operational Medicine Research & Development (Air Force)	0.141	4.907	1.983

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

FY 2013 Accomplishments:

Completed development/animal testing of thoracic aortic balloon occlusion prototype, worked with industry and academia to transition to next phase of testing. Completed several Congressionally funded projects related to use of a mobile technology for management of diabetes which resulted in completion of the technical integration of a FDA approved diabetes management mobile application with a civilian Electronic Health Record (EHR); continued development of a comprehensive registry for Autism Spectrum Disorders (ASD) in Central Ohio; identified 24 noncoding DNA variants for autism susceptibility; and sustained expanded autism clinical diagnostic and treatment services for Wright Patterson AFB families in collaboration with Dayton Children's Hospital. Completed work on (7) congressionally funded diabetes research projects sustained: Pediatric Weight Management Center at Wilford Hall Medical Center; continued expansion of the nationally recognized obesity and diabetes prevention program (Group Lifestyle Balance Program) for beneficiaries with creation of online version of 16 week course and six AFMS personnel achieved Group Lifestyle Balance Master Trainers certification; Joint Base Andrews, one of two AFMS facilities, received American Diabetes Association Recognition status for the Military Treatment Facility (MTF)'s Diabetes Self-Management Education Program. Completed research efforts related to the pathophysiology of traumatic corneal scar injury in

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 285A / *Operational Medicine Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
an animal model and positively demonstrated that use of immunomodulatory agents after photorefractive keratotomy decreased incidence of corneal haze, paving the way for revision of DoD clinical practice guidelines. Using AF DHP RDT&E, funded/initiated two personalized medicine studies to include continuation of the work to identify new autism susceptibility variants and expansion of the ASD registry, as well as a project to identify genes for which obesity modifies the association with asthma. ***FY 2014 Plans:*** Continue patient centered/personalized medicine research efforts related to autism and obesity. Align resources with academia and other health agencies to evaluate outcomes of standardized diabetes prevention initiatives, including online resources. Through intramural efforts, determine if a medication therapy management program for patients with chronic pain at a large Military Treatment Facility will reduce costs and improve outcomes. Evaluate personalized prevention and treatment efforts related to Patient-Centered Precision Care. Building on previous work, identify opportunities for advanced development of mobile health application technologies within the MHS for personalized disease prevention and management. Begin evaluation of utilization and effectiveness of current AF mental health/family support programs for the purposes of identifying gaps and possible solutions to areas such as marital discord, family maltreatment, binge drinking, and suicide. ***FY 2015 Plans:*** Building on previous work, concentrate on the use of mobile health technologies to integrate evidenced-based solutions into clinical practice and the EHR to positively influence behavior and promote health. Further the work related to AF mental health/ family support by pilot testing proposed solutions to specified issues in an effort to translate solutions into AFMS wide practice. Determine the timeliness of communication (information exchange) of clinical information and the effectiveness of communication processes to identify gaps or potential patient safety issues that may impact outcomes to include morbidity and mortality.			
Accomplishments/Planned Programs Subtotals	0.141	4.907	1.983

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 285A / *Operational Medicine Research & Development (Budgeted) (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 2015 Defense Health Program			Date: March 2014
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*	

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
307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)*	14.335	0.393	15.353	12.558	-	12.558	14.173	17.653	19.333	19.700	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

This project area seeks to deliver an improved Force Health Protection capability across the full spectrum of operations with research that prevents injury/illness through improved identification and control of health risks. Under Force Health Protection, sub-project areas include: Directed Energy, Occupational and Environmental Health, and Advanced Diagnostics/Therapeutics. Research in the Directed Energy (DE) sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health (OEH) sub-project area involves the assessment and implementation of innovative new technologies that not only give Air Force Medical Service personnel battlefield situational awareness of Occupational and Environmental Health Hazards, but which also enables effective surveillance, detection and mitigation. Other OEH areas of interest include infectious disease and food and water surveillance. Advanced Diagnostics/Therapeutics research sub-project areas include Personalized Medicine/Genomic Medicine. The Personalized Medicine/Genomic Medicine sub-project area supports the development of systems advancing the delivery of 'Omic-informed personalized medicine and emphasizes targeted prevention, diagnosis, and treatment.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force)	0.393	15.353	12.558
Description: This project area seeks to deliver an improved Force Health Protection capability across the full spectrum of operations with research that prevents injury/illness through improved identification and control of health risks. Under Force Health Protection, sub-project areas include: Directed Energy, Occupational and Environmental Health, and Advanced Diagnostics/Therapeutics. Research in the Directed Energy (DE) sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health (OEH) sub-project area involves the assessment and implementation of innovative new technologies that not only give Air Force Medical Service personnel battlefield situational awareness of Occupational and Environmental Health Hazards, but which also enables effective surveillance, detection and mitigation. Other OEH areas of interest include infectious disease and food and water surveillance. Advanced Diagnostics/ Therapeutics research sub-project areas include Personalized Medicine/Genomic Medicine. The Personalized Medicine/Genomic Medicine sub-project area supports the development of systems advancing the delivery of 'Omic-informed personalized medicine and emphasizes targeted prevention, diagnosis, and treatment.			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

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

FY 2013 Accomplishments:

Completed follow-on studies assessing the relationship between inhalation exposure to alternative jet fuels and noise. Completed the nanomaterial exposure chamber prototype, test scenarios for testing occupational airborne exposures. Used the panel of proteins identified in laser exposure studies to characterize retinal laser injuries. Expanded study of high-powered microwave exposures to establish dose-response relationships. Furthered the evaluation of foreign made, clinical, lasers to validate that the devices meet U.S. standards for lasers. Performed field testing of smaller/more capable sensors for remote environmental and physiological monitoring. Continued to evaluate personal cooling technologies that can prevent heat stress in extreme environments in field conditions. Completed development of technology and methods to analyze soil samples for radionuclide presence and transition to AF Radiologic Assessment Team, whose mission is DoD-unique. Proceeded with the development of a compact, insulated, leak-proof, laboratory-approved transport system for shipping food samples from remote locations to the laboratory. Continued research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Completed enrollment of 2000 AFMS participants in the PC2-Z Clinical Utility Study. Initiated 'omics research studies on genetic risk testing and health coaching, statin pharmacogenomics and epigenetic biomarkers of stress at high altitude. Survey of AFMS personnel on genomics education and the application of genetic testing to clinical care conducted. Completion of charter for the Precision Care Advisory Panel (PCAP), a joint service committee to provide service-specific operational and policy guidance for the implementation of personalized medicine within the DoD.

FY 2014 Plans:

Develop a retinal injury atlas database for use by clinicians, and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Continue the development of prototype devices to detect and quantify lasers used to illuminate aircraft and qualify the health threat of laser illumination to aircrew. Integrate the health risk assessments produced from the prototype devices to locate laser energy sources into command and control. Work with MAJCOMS to test smaller/ more capable sensors for remote environmental and physiological monitoring in various operational settings. Apply smaller/ more capable, autonomous, field deployable, sensors to enable data transfer. Test miniaturized sensors to identify hypoxic/toxic aircrew. Initiate the research and development for the integration and demonstration of advanced medical, physiological status sensors, and exposure sensors technologies in a laboratory environment to prepare them for aircraft integration. Complete the development of a compact, insulated, leak-proof, laboratory-approved transport system for shipping food samples from remote locations to the laboratory. Finish the research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Continue the study of high-powered microwave exposures to establish dose-response relationships. Complete the development of prototype devices to detect and quantify lasers used to illuminate aircraft and qualify the health threat to aircrew. Test these sensors on fixed wing and rotor wing aircraft in operational like environments. Further the evaluation of foreign made, clinical, lasers to validate that the devices meet U.S. standards for lasers. Perform field testing of smaller/more capable sensors for remote environmental and physiological monitoring. Proposed expansion of Genomic Studies to include analysis of conditions

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
with operational importance, including obesity and insomnia. Analysis of genomics survey data to identify gaps in genomic education, and development of educational programs to correct these gaps. Utilization of patient modeling algorithms to identify pharmacogenomic interventions that can improve patient health and reduce healthcare costs. Analysis of methodologies and challenges associated with the establishment of a genome data repository for future implementation of genomic medicine. Further participation in the National Human Genome Institute eMERGE Network through pharmacogenomic research projects. ***FY 2015 Plans:*** Complete the development of a retinal injury atlas database for use by clinicians, and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Complete the development of prototype devices to detect and quantify lasers used to illuminate aircraft and qualify the health threat of laser illumination to aircrew. Work with MAJCOMS to test smaller/more capable sensors for remote environmental and physiological monitoring in various operational settings. Apply smaller/more capable, autonomous, field deployable, sensors to enable data transfer. Complete the evaluation of and test of miniaturized sensors to identify hypoxic/toxic aircrew. Continue the research and development for the integration and demonstration of advanced medical, physiological status sensors, and exposure sensors technologies in a laboratory environment and conduct initial testing for integration aboard aircraft. Continued support for the Clinical Utility Study to include initial analysis of impact of genomic risk data on study participants. Analysis of recruited cohorts for diseases and conditions of operational importance. Implementation of genomic education program at test facility to measure impact of education on genetic test utilization, clinical care, and patient outcomes. Pharmacogenomic demonstration projects to test the impact on patient health and healthcare costs. Investigation of methodologies and requirements for bioinformatics tools and processes needed for the integration of genomic data into clinical workflow.			
Accomplishments/Planned Programs Subtotals	0.393	15.353	12.558

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 307B / *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (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 2015 Defense Health Program			Date: March 2014
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / *Medical Technology Development*	Project (Number/Name) 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*	

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
308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)*	2.796	0.051	4.769	4.699	-	4.699	4.185	4.159	4.554	4.641	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Expeditionary Medicine Research & Development (Air Force)	0.051	4.769	4.699

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

FY 2013 Accomplishments:

Completed the FDA approval process for the Trauma Specific Vascular Injury Shunt. Applied predictive algorithms for the continuous non-invasive monitoring of patient status in order to predict actionable interventions. Evaluated clinical utility of prototype laser device for hemorrhage control and tissue cutting and archived results for future inquiries. Transitioned Virtual Medical Trainer (09) software platform for preparing leaders and decision makers to hone communication and planning skills for interagency disaster response efforts. Began research on predicting blood needs using pre-hospital vital signs, and novel

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 308B / *Expeditionary Medicine Research & Development (Budgeted) (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
techniques for infection control of traumatic wounds to include a bioelectric dressing and topical agent for antibiotic resistant bacteria. ***FY 2014 Plans:*** Transition the Trauma Specific Vascular Injury Shunt device, and proceed to fielding and procurement. Initiate research on therapeutic drugs given by first responders to slow body functions providing more time to transfer of seriously wounded to definitive care. Continue research on a novel technique for infection control of traumatic wounds, predicting blood needs using pre-hospital vital signs, and hemorrhagic shock resuscitation. Pursue additional research to mature the multi-channel negative pressure wound treatment system and continue to address advanced development issues. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics ***FY 2015 Plans:*** Build on ongoing work with concentration on therapeutic interventions to sustain life through transfer to definitive care. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics.			
Accomplishments/Planned Programs Subtotals	0.051	4.769	4.699

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

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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 0603115HP / *Medical Technology Development*	Project (Number/Name) 309A / *Regenerative Medicine (USUHS)*	

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
309A: *Regenerative Medicine (USUHS)*	6.877	-	7.294	9.190	-	9.190	9.489	9.649	9.823	7.945	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Regenerative Medicine (USUHS)	-	7.294	9.190

Description: The Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center. The CNRM has established 11 research cores and funded over 100 research projects.

FY 2013 Accomplishments:

CNRM accomplish key objectives in FY13:

• Under the Acute Studies Core, collaborative agreements were executed with VCU and UMD to expand acute patient enrollment at local area sites with imaging.

• Advanced neuroimaging capabilities, including: acquisition of simultaneous human MRI and PET, improving diffusion imaging for clinical requirements, testing novel PET ligands for inflammation and neurodegeneration. The CNRM Siemens Biograph mMR System was the second installed in a U.S. clinical setting and the first to scan a human patient using simultaneous MRI and PET. Two hundred and forty three subjects have been enrolled.

• The Translational Imaging core continues to develop novel scanning protocols for rodent microPET, microCT, and 7T MR, especially as relevant to specialized needs for TBI pathologies and with consideration of comparison with the human scanning applications.

• The Pre-clinical Models Core continues to be used heavily. Development of a state-of-the-art blast facility for animal model testing at USU has been initiated and anticipated to be fully operational fall 2014.

• State-of-the-art neuropathological center established under Dr. Dan Perl with infrastructure for brain specimen acquisition, evaluation, storage, and distribution. This brain repository is the first dedicated to military service members.

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
• The Informatics core has implemented the TBI clinical database with policies for submission and sharing across CNRM investigators and institutions (USU, WRNMMC, and NIH) aligned with the developing Federal Interagency TBI Research database. • The Image Processing Core has nearly completed implementing a database platform for managing the CNRM Imaging Repository with integration of the database with the Informatics database addressed following initial deployment. • Clinical studies have explored inflammation and neurodegeneration biomarkers, including auto-antibodies that persist in blood and allow identification of transient responses to CNS damage. • Pre-clinical studies across multiple TBI models are identifying mechanisms of CNS damage and repair, including molecular and cellular substrates of neuroregeneration and neuroplasticity. The range of TBI models is particularly designed to address the spectrum of injury experienced by military service members. • To date, CNRM has published over 130 peer-reviewed publications. In addition, CNRM researchers have presented at numerous national and international conferences. CNRM received 24 proposals in response to a FY13 proposal call. After scientific review and administrative approval, 10 two-year projects were funded in FY13. CNRM approved an additional 3 human use protocols so far in FY13. FY13 efforts toward the next expected research proposal opportunity had to be put on hold due to loss of all CNRM FY13 RDTE funding.			
FY 2014 Plans: CNRM objectives include: (1) Continue interdisciplinary, collaborative studies that bring together expertise across USU, WRNMMC, and intramural NIH to address the highest priority TBI research in diagnosis through treatment and recovery as relevant to military service members; (2) Continue operational capability of all Cores to provide efficient research infrastructure with high quality resources and technical expertise; (3) Fund start-up research of one new USU Radiology faculty member to maintain translational neuroimaging capability; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY14-15 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host internal CNRM data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research.			
FY 2015 Plans: The MCNCoE has been merged in the CNRM beginning in FY 2015 and the CNRM will absorb the research work of the MCNCoE. CNRM objectives include: (1) Continue interdisciplinary, collaborative studies that bring together expertise across USU, WRNMMC, and intramural NIH to address the highest priority TBI research in diagnosis through treatment and recovery as			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 309A / *Regenerative Medicine (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
relevant to military service members; (2) Continue operational capability of all Cores to provide efficient research infrastructure with high quality resources and technical expertise; (3)Fund start-up research of one new USU Radiology faculty member to maintain translational neuroimaging capability; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY14-15 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host internal CNRM data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research.			
Accomplishments/Planned Programs Subtotals	-	7.294	9.190

C. Other Program Funding Summary ($ in Millions)

Line Item	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
• BA-1, 0806721HP: *Uniformed Services University of the Health Sciences*	8.330	8.755	9.022	-	9.022	9.293	9.395	9.555	9.717	Continuing	Continuing

Remarks

FY 2013 Program Decremented during Sequestration (-$0.165 million)

D. Acquisition Strategy

N/A

E. Performance Metrics

Center for Neuroscience and Regenerative Medicine: In FY13 through FY15, identify, design protocols, perform scientific and program reviews, and conduct research in Clinical Core activities such as Phenotyping, Imaging and Imaging Analysis, to aid in patient diagnosis and evaluation.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 373A / *GDF - Medical Technology Development*	

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
373A: *GDF - Medical Technology Development*	48.595	79.544	145.961	113.048	-	113.048	116.775	134.176	149.232	162.193	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 - Medical Technology Development provides funds for promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small-scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. Research in this PE is designed to address 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 and execution is peer reviewed and fully 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. 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 PE includes hemorrhage (bleeding) control, resuscitation, blood products, forward surgical and intensive critical care, en route care, military medical photonics, diagnosis and treatment of brain injury, environmental health and performance, physiological and psychological health, injury prevention and reduction, medical simulation and training, health informatics, and rehabilitation.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: GDF – Medical Technology Development	79.544	145.961	113.048
Description: Funds provide for the development of medical technology candidate solutions and components of early prototype systems for test and evaluation. Promising drug and vaccine candidates, knowledge products, and medical devices and technologies are selected for initial safety and effectiveness testing in small scale human clinical trials.			
FY 2013 Accomplishments: Medical training and health information sciences efforts improved healthcare access, availability, continuity, cost effectiveness, and quality. Specific efforts focused on research investigating the utility of augmented reality (feedback through visual displays or sense of touch) as military healthcare personnel training tools, particularly current training techniques versus augmented reality methods. Efforts included out-patient, home rehabilitation and educational simulation technologies for wounded Service members. Health Information Technology efforts were focused on advancing analytics through the exploration of clinical decision support within nursing. Military infectious diseases research supported multi-year first-in-human initial safety clinical studies and expanded safety and initial effectiveness clinical studies in antimicrobial countermeasures for antibacterial and anti-biofilm agents. Clinical studies for			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
biomarker, multi-drug resistant organisms (MDRO) detection, and diagnostic assay technologies for wound infection prevention and management were started during FY11/12 and supported in FY13. Military operational medicine efforts focused on: validation of dose response curves for noise induced hearing loss, use of animal models to determine protective capabilities within the inner ear using antioxidants and determine the most effective doses and maximum time delays to prevent noise-induced hearing loss. This information will result in significant reductions in noise-related compensation claims to the Department of Veterans Affairs and facilitate the return-to-duty for injured Warfighters. Additional efforts focused on: performance validation of the surface-mounted clay add-on device using live-fire tests of military-grade armor systems providing the first biomedically valid behind-body-armor design standard as a replacement to the current Department of Justice standard. This will allow equipment developers to design body armor appropriate to the specific needs of each region of the body. Other efforts entailed: (1) conducting human clinical trials of the Hydration Status Monitor (a device to monitor fluid intake and electrolyte imbalance) for diagnostic and biological testing; (2) field studies to determine the effect of vitamin D and calcium supplements on nutritional status of Warfighters leading to improved bone health and mitigating the potential for bone stress fractures; and (3) validation of constructs of Warfighters performance, mental strength and psychological well-being using current psychological assessment tools providing a validated portfolio of self-reporting instruments capable of assessing various psychological attributes of military personnel, thereby enhancing psychological resilience. Combat casualty care research pursued successful studies, from FY11-13, such as the study of enhanced oxygen delivery in acute spinal cord injury, the plasma volume expander, red blood cell storage research and started technology development of platelet-derived agents to stop bleeding and neuromodulation (a treatment that delivers either electricity or drugs to nerves in order to change their activity) for the repair of traumatic injuries to the brain. Due to sequestration, a program announcement in the areas of en route care and forward surgical and intensive battlefield care was deferred. Clinical and rehabilitative medicine advanced studies in neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury rehabilitation, pain management, and rehabilitation after traumatic injury. Initiated studies to support development and preclinical and pilot/early-phase clinical evaluations of candidate technologies for restoration and rehabilitation strategies and medical products. Specific focus areas included (1) neuromusculoskeletal injury rehabilitation strategies and devices, prosthetics (artificial device that replaces a missing body part), and the prevention of heterotopic ossification (bone formation in soft tissue following injury); (2) novel therapeutics and devices for pain management; (3) regenerative medicine-based approaches for limb and digit salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, genitourinary (genital and urinary organs) restoration and addressing compartment syndrome (muscle, nerve and vascular			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
damage due to swelling post-injury); and (4) restoration and rehabilitation of sensory system injury, including vision, hearing and balance injury and dysfunction. Sensory system efforts to be initiated in FY13 were postponed to FY14 due to sequestration.			
FY 2014 Plans: Medical training and health information sciences research efforts are working in two primary research portfolios: Medical Simulation and Training, and Health Informatics and Information Technology. Medical simulation and training focus is on research opportunities identified by the Combat Casualty Training Consortium (CCTC), which is identifying potential gaps where simulation technology can be utilized to support combat medic training and has the impact of reducing and refining live-tissue training. Additional emphasis is being placed on the technologies to teach and train effective team communication. The concept of an open-source tissue model for developers and end-users to facilitate cohesive content delivery for manikins or virtual models is in progress. The medical practice initiative efforts are aimed at understanding healthcare personnel skill decay through improved team training and its correlation with skill. Health informatics and information technology conducts research on risk reduction within the Military Health System to identify ways to reduce potential near- and long-term cost of information technology and systems, as well as the transition of a joint Department of Veterans Affairs (VA) and DoD integrated Electronic Health Record (iEHR). Clinical decision support exploration within nursing continues within the portfolio. The military infectious diseases research program is funding one multi-year, clinical study for development of an antibacterial drug against multiple drug resistant bacteria in antimicrobial countermeasures; one host/pathogen biomarker project in wound infection prevention and management for detection of bacterial infection in wounds; and one diagnostic project in wound infection prevention and management for the detection of bacterial infections in wounds. Military operational medicine research will be continuing medical technology development efforts initiated in FY13 in 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 and treatment of deployment-related psychological health problems, diagnosis and treatment of PTSD, military family and Warfighter resilience, suicide prevention, pulmonary health (pertaining to the lungs) 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 Committee will be issuing program announcements with topics in the areas of physiological health, injury prevention and reduction, psychological health, and environmental health and protection. Combat casualty care research is pursuing successful studies from FY12 and FY13, such as the study of enhanced oxygen delivery in acute spinal cord injury, the plasma volume expander, red blood cell storage research, platelet-derived agents to stop bleeding and neuromodulation (a treatment that delivers either electricity or drugs to nerves in order to change their activity), and			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
conducting technology development of agents to improve resuscitation after severe bleeding, foams to stop internal bleeding, and real-time, physiologic monitoring across the battle space. Clinical and rehabilitative medicine will be advancing studies in neuromusculoskeletal injury rehabilitation, pain management, and sensory system restoration and rehabilitation after traumatic injury. Clinical and rehabilitative medicine will be continuing studies started in FY13 to support development and preclinical and pilot/early phase clinical evaluations of candidate technologies for restoration and rehabilitation strategies and medical products. Specific focus areas include: neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury rehabilitation strategies and devices; prosthetics (artificial device that replaces a missing body part); neural interfaces (electrodes wired into the brain) and the prevention of heterotopic ossification (bone formation in soft tissue following injury); 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 (genital and urinary organs) restoration; and restoration and rehabilitation of sensory system injury, including vision, hearing and balance injury and dysfunction. ***FY 2015 Plans:*** Medical simulation and training efforts will augment the Combat Casualty Training Initiative and build upon the Advanced Modular Manikin (AMM) platform core by researching interchangeable peripherals that can be optimized for specific training needs. Research will be targeted towards building an open source tissue model and virtual reality resources that will be open to developers and end-users, allowing them to focus on content creation into a variety of simulation system tools. Medical Simulation will support research to improve the realism of virtual standardized patients (avatars) used for high volume scenario rehearsal, through improved artificial intelligence and realistic body language within a medical context. Medical simulation will research effective ways to interface with technology through gestures or facial expressions. With the emergence of the Defense Health Agency (DHA) health informatics and health information technology research will move to PE 0604110 to emphasize transition to advanced development. Military infectious diseases research will have no new starts in FY15 but will continue to support projects started in FY14. Within antimicrobial countermeasures, a first-in-human study for development of an antibacterial drug against multiple drug resistant bacteria will complete and submit an Investigational New Drug Application to the Food and Drug Administration (FDA). The wound infection prevention and management host/pathogen biomarker project for detection of bacterial infection in wounds and diagnostic project for the detection of bacterial infections in wounds will complete laboratory studies and initial animal studies to confirm ability and accuracy to detect. Military operational medicine research will support medical technology development efforts initiated in FY13 and FY14 to: establish and validate guidelines for nutrition and dietary supplements; improve Warfighter performance and sustainment in			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
extreme environments (such as extreme heat, cold, or altitude); establish return-to-duty/medical standards criteria; validate blast injury models and performance standards for protections systems; develop diagnostics and metrics for hearing loss and protection; conduct clinical trials to prevent alcohol and substance abuse; improve diagnosis and treatment of deployment-related psychological health problems; develop improved diagnostics and treatments for post-traumatic stress disorder (PTSD); conduct clinical trials to enhance military family and Warfighter resilience; conduct clinical trials to enhance suicide prevention; establish and validate guidelines for pulmonary health in the deployed environment; and develop and validate guidelines to mitigate blast exposure during breaching. Program announcements will be forthcoming with topics in the areas of physiological health, injury prevention and reduction, psychological health, and environmental health and protection. Combat casualty care research will pursue successful studies from FY13 and FY14, such as clinical assessment of new hemostatic agents (products that stop bleeding) that can control severe internal bleeding and be administered by first responders at or near the point of injury; development of multiple new TBI diagnostic approaches that when used together provide a more comprehensive diagnosis than what is currently available; development of cell therapies for lung injury; development of military medical photonics; and research to support development of a virtual intensive care unit (ICU) linking patient movement and medical support providers at all levels within the theater of operations. Clinical and rehabilitative medicine will transition current efforts and down-select products to advanced development for neuromusculoskeletal (system of nerves, muscles, and bones that enable movement), injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Clinical and rehabilitative medicine will continue to support development of preclinical and pilot/early-phase clinical evaluations of candidate technologies for restoration and rehabilitation strategies and medical products. Specific focus areas will include: neuromusculoskeletal injury rehabilitation strategies and devices; prosthetics; (artificial device that replaces a missing body part); 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 and the prevention and treatment of heterotopic ossification (bone formation in soft tissue following injury); novel therapeutics and devices for pain management; regenerative medicine-based approaches for limb and digit salvage; craniomaxillofacial (skull, face and jaw) reconstruction; scarless wound healing; repair of skin injury resulting from burns; composite tissue allotransplantation (tissue/organ transplantation between genetically different individuals) and associated immune system modulation technologies; genitourinary (genital and urinary organs) restoration; and restoration and rehabilitation of sensory system injury, including vision, hearing and balance injury and dysfunction.			
Accomplishments/Planned Programs Subtotals	79.544	145.961	113.048

C. Other Program Funding Summary ($ in Millions)

N/A

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 373A / *GDF - Medical Technology Development*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

Principal investigators will participate in In-Progress Reviews, DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and are subjected to Program Office and/or 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 medical technology development funding will be the attainment of maturity level that is typical of Technology Readiness Level 6 or the equivalent for knowledge products.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 378A / *CoE-Breast Cancer Center of Excellence (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
378A: *CoE-Breast Cancer Center of Excellence (Army)*	9.722	3.355	10.338	8.664	-	8.664	7.299	5.709	4.068	1.777	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Breast Cancer Center of Excellence	3.355	10.338	8.664
Description: Provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.			
FY 2013 Accomplishments: The Breast Cancer CoE, also referred to as the Clinical Breast Care Project (CBCP), enrolled subjects seen at the Breast Translational Research Center in the core CBCP protocols. The CBCP acquired specimens according to approved research protocols, and conducted analyses that included but was not limited to: risk factors for developing breast cancer, effectiveness of various modalities of treatment, and actual risk of developing cancer. The CBCP enhanced the acquisition and banking of breast tissue, lymph nodes, serum/plasma and other blood derivatives from informed and consented donors to be the foundation for their translational research program. Initiatives within the translational research program included generation of a complete genomic DNA sequence from up to 60 breast cancer cases and utilization of antibody tissue staining and analysis to generate clinically relevant profiles of breast tumors to better stratify the disease in terms of prognosis and treatment options. The Biomedical Informatics Group supported the research activities of the Center as well as carried out research into new algorithms and methods to improve the detection and treatment of breast cancer.			
FY 2014 Plans: In FY14, the Breast Cancer CoE (Army), also referred to as the Clinical Breast Care Project (CBCP), at Walter Reed National Military Medical Center (WRNMMC) Bethesda is continuing to accrue subjects annually to the core CBCP protocols. The CBCP is continuing to acquire, through consented protocol, specimens (normal and abnormal breast tissues and tumors, lymph nodes, metastatic (spread of a cancer from one organ or part to another non-adjacent organ or part) deposits, blood and its components, bone marrow) annually from subjects with all types of breast diseases and cancer. The repository is continuing to be utilized			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 378A / *CoE-Breast Cancer Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
as the basis for all molecular analyses in CBCP labs, as outlined in the CBCP Core Protocols allowing for global expression analysis of the DNA, RNA, and protein features and as the basis for intramural and extramural collaborations for secondary usage research. CBCP is performing whole-genome DNA sequencing on DNA from 60 cases of breast cancer; continuing the development of and support of a robust laboratory information management system to ensure proper tracking of data acquisition and a clinically relevant and laboratory research-linked prospective, database to support translational research and ultimately support physician decision making; continuing development of an analytical system for integrative data analysis and mining, and further refining a breast knowledge base to support research activities in CBCP; utilizing Clinical Laboratory Workflow System as the data analysis tool and integrating Armed Forces Health Longitudinal Technology Application (AHLTA) data from the military's main electronic medical record; identifying research subjects at high-risk for development of breast cancer, and employing risk reduction strategies; completing genomic and proteomic analysis of samples collected at various developmental stages of breast cancer; and is presenting findings in peer-reviewed publications and at national meetings. ***FY 2015 Plans:*** The Clinical Breast Care Project will continue performing whole genome DNA sequencing on DNA from cases of breast cancer; continue development of and support of a robust laboratory information management system to ensure proper tracking of data acquisition and a clinically relevant and laboratory research-linked prospective, database to support translational research and ultimately support physician decision making; continue development of an analytical system for integrative data analysis and mining, and further refine a breast knowledge base to support clinical and research activities in the Breast Cancer Center of Excellence; utilize Clinical Laboratory Workflow System as the data analysis tool and integrated Armed Forces Health Longitudinal Technology Application (AHLTA) data from the military's main electronic medical record; identify and counsel patients at high risk for development of breast cancer, and employ risk reduction strategies; perform targeted research by conducting DNA and protein analysis of Stages I, II, and III breast cancer, cancer found in the breast ducts and lobules, and pre-malignant breast lesions; and will present findings in peer-reviewed publications and at national meetings.			
Accomplishments/Planned Programs Subtotals	3.355	10.338	8.664

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 378A / *CoE-Breast Cancer Center of Excellence (Army)*

E. Performance Metrics

Performance is judged on the number of active protocols, the number of articles that appear in peer-reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 379A / *CoE-Gynecological Cancer Center of Excellence (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
379A: *CoE-Gynecological Cancer Center of Excellence (Army)*	8.494	2.931	9.033	7.570	-	7.570	6.377	4.989	3.555	1.552	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Gynecologic Cancer Center of Excellence (Army)	2.931	9.033	7.570

Description: The Gynecologic Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecologic disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecologic disease.

FY 2013 Accomplishments:

The Gynecologic Cancer Center of Excellence extended previous studies of gynecologic cancer metastasis (spread of cancer from one organ or part to another non-adjacent organ or part) and recurrence, patient survival, drug resistance and racial disparities in cancer outcome by completing clinical assay and validation studies of the most promising biomarker panels. Molecular-based prediction models with the best sensitivity, specificity, as well as positive and negative predictive value were promoted for specific clinical indications and deployment in independent surgical and/or biopsy specimens and biofluids (biological fluids like blood, urine, breast milk, and cerebrospinal fluid). Data forthcoming from molecular studies (DNA, RNA, protein) was integrated utilizing computational biology to elucidate systems-level regulatory mechanisms underlying metastasis and recurrence in endometrial (membrane lining the uterus) cancer along with drug resistance, tumor progression, and survival in primary compared with metastatic and recurrent ovarian cancers. Approximately 600 patients with gynecologic cancer undergoing surgery for primary or recurrent disease as well as additional control patients with benign conditions undergoing a hysterectomy (surgical removal of the uterus) were enrolled on the Tissue and Data Acquisition Network (TDAN) protocol to collect various types of tumor and normal tissues, blood for extraction of DNA, RNA and microRNA, as well as serum and urine. TDAN specimens were linked with detailed clinical, treatment, outcome and life-style questionnaire data. The prospectively collected TDAN clinical specimens and epidemiologic data will be leveraged for discovery and validation studies associated with the Early Detection and Molecular Profiling Programs in FY14. Preclinical models were developed to optimize the chemopreventive (the use of agents

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 379A / *CoE-Gynecological Cancer Center of Excellence (Army)*

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

to prevent the development of cancer) activity of hormone and vitamin D strategies for deployment in clinical trials of endometrial cancer. Our therapeutics program evaluated novel vaccines in ovarian and endometrial cancer, and novel designs for tailored salvage therapy trials to direct endometrial or ovarian cancer patients with specific molecular defects/alterations to specific classes of molecular targeting agents. An intervention study was initiated to evaluate the effects of stress intervention on recurrence of disease in ovarian cancer, and to evaluate biomarker changes.

FY 2014 Plans:

The Gynecologic Cancer Center of Excellence will conduct retrospective longitudinal (observations over long periods of historical time) and prospective (observations during a current or future study period) validation studies of biomarker candidates from our previous studies of gynecologic cancer metastasis and recurrence, patient survival, drug resistance and racial disparities in cancer outcome. These investigations rely on collected specimens as well as external biospecimen (materials taken from the human body, such as blood, plasma, urine, etc., that can be used for diagnosis and analysis) collections, such as the Gynecologic Oncology Group (GOG)-249 randomized treatment trial and the Prostate, Lung, Ovarian and Colorectal (PLCO) trial. The candidates identified in our preclinical models are being evaluated in human trials as surrogates/predictors of response to progesterone/progestin and vitamin D. Hypotheses generated from systems-level integration of molecular studies are being evaluated using models of ovarian and endometrial (pertaining to the lining of the uterus) cancer. These novel hypotheses establish the framework for the next generation of molecularly targeted therapeutics and diagnostic therapy for gynecologic cancer patient management. Novel molecular candidates are being incorporated into a newly established ensemble of safety and efficacy gynecologic cancer clinical trials aimed at directing endometrial or ovarian cancer patients with specific molecular defects/alterations to tailored molecular targeting regimens, and testing new therapeutics for treatment of newly diagnosed and recurrence/refractory (resistant, unresponsive to surgery or therapy) cancer patients. The intervention trial will remain open to accrual to evaluate the effects of stress intervention on recurrence of disease in ovarian cancer, and to evaluate biomarker changes in serial biofluids (biological fluids like blood, urine, breast milk, and cerebrospinal fluid).

FY 2015 Plans:

The Gynecologic Cancer Center of Excellence will continue conducting retrospective longitudinal and prospective validation studies of biomarker candidates from our previous studies of gynecologic cancer metastasis and recurrence, patient survival, drug resistance and racial disparities in cancer outcome. These investigations will rely on collected specimens as well as external biospecimen (materials taken from the human body such as blood, plasma, urine, etc that can be used for diagnosis and analysis) collections, such as the Gynecologic Oncology Group (GOG)-249 randomized treatment trial and the Prostate, Lung, Ovarian and Colorectal (PLCO) trial. The candidates identified in preclinical models will be evaluated in human trials as surrogates/predictors of response to progesterone/progestin and vitamin D. Hypotheses generated from systems-level integration of molecular studies will be evaluated using models of ovarian and endometrial cancer. These novel hypotheses establish the framework for the next generation of molecularly targeted therapeutics and diagnostic therapy for gynecologic cancer patient management. Novel molecular candidates will be incorporated into a newly established ensemble of safety and efficacy gynecologic cancer

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 379A / *CoE-Gynecological Cancer Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
clinical trials aimed at directing endometrial or ovarian cancer patients with specific molecular defects/alterations to tailored molecular targeting regimens, and testing new therapeutics for treatment of newly diagnosed and recurrence/refractory (resistant, unresponsive to surgery or therapy) cancer patients. The intervention trial will remain open to accrual to evaluate the effects of stress intervention on recurrence of disease in ovarian cancer, and to evaluate biomarker changes in serial biofluids.			
Accomplishments/Planned Programs Subtotals	2.931	9.033	7.570

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

Performance of the Gynecological Cancer Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer-reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 381A / *CoE-Integrative Cardiac Health Care Center of Excellence (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
381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*	3.584	1.238	3.811	3.594	-	3.594	3.520	3.368	3.214	1.747	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Cardiac Health Center of Excellence (Army)	1.238	3.811	3.594
Description: The focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by incorporating biomolecular research to detect CVD at an early stage, and identifying markers of increased risk for heart attack in service members.			
FY 2013 Accomplishments: The Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), collaborated with the Physical Medicine Department at the Walter Reed National Military Medical Center (WRNMMC) to conduct a comparative cohort study to determine comprehensive CVD risk assessment in Wounded Warriors with traumatic war amputations, the first study of its kind. In another first of its kind, ICHP performed a randomized prospective study to determine the effectiveness of the ICHP CVD risk reduction model on endothelial (blood vessel lining), diastolic (blood pressure after the contraction of the heart), and molecular functions in patients with low 10-year CVD risk but high lifetime risk for CVD. Many active duty members are unaware that they have low short-term risk but high lifetime risk. In another study, the CoE tested the feasibility of a novel finger-stick point-of-care technology and the ICHP CVD risk reduction model to generate disease maps in pre-diabetic ICHP patients			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 381A / *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
at risk for CVD. In examining a novel scientific process, ICHP utilized a modified serum DNA amplification process in samples from the DoD serum repository. If successful, the CoE will obtain DNA from the DoD serum repository samples for future studies. This will be the first step to use this technique to identify young military members at risk for heart attack. ICHP is continuing development of a robust data management system. This enhanced integrative data collection is designed to capture a full picture of the individual to include physiological, behavioral, biochemical and molecular information. Our platform gathered an expansive number of data points that when leveraged can create new tools and refine processes to better define wellness, predict disease, empower patients, transform delivery to improve quality of life and deliver personalized CVD prevention in the military population. ICHP's vision of lifelong cardiovascular health supports the Military Health System (MHS) Strategic Plan creating value to the MHS. ***FY 2014 Plans:*** The Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), is continuing research studies initiated in FY12-13. Data collection from approved FY12-13 protocols is continuing and being analyzed and synthesized. ICHP is translating and communicating best practices to the services in order to augment clinical practice. Utilizing our Knowledge to Action framework, ICHP are incorporating findings from studies for new hypothesis generation and development of new protocols for FY14-18 to expand the use of point-of-care technology in the ICHP model, whole genome sequencing for early CVD detection, and investigating the use of serum biomarker maps for personalized CVD risk assessment in Wounded Warriors. ***FY 2015 Plans:*** The Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), will continue research studies initiated in FY13-14. Data collection from approved FY13-14 protocols will be analyzed and synthesized. ICHP will continue translating and communicating best practices to the services in order to augment clinical practice. Utilizing our Knowledge to Action framework, ICHP will continue incorporating findings from our studies for new hypothesis generation and development of new protocols for FY15-19 to expand the use of point-of-care technology in the ICHP model, whole-genome sequencing for early CVD detection, and investigating the use of serum biomarker maps for personalized CVD risk assessment in Wounded Warriors.			
Accomplishments/Planned Programs Subtotals	1.238	3.811	3.594

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 381A / *CoE-Integrative Cardiac Health Care Center of Excellence (Army)*

D. Acquisition Strategy

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

E. Performance Metrics

Integrative Cardiac Health Care Center of Excellence performance is judged on high impact discoveries, development of new diagnostic and treatment strategies, identification of emerging issues of disease feature and patterns, the amount of extramural funding received, the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of medical students, residents and post-doctoral fellows in the Military Health System.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 382A / *CoE-Pain Center of Excellence (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
382A: *CoE-Pain Center of Excellence (Army)*	2.715	0.937	2.888	-	-	-	-	-	-	-	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

The Pain Center of Excellence (Army) examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration. The Pain Center of Excellence is an integral part of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) whose mission is to become a referral center that supports world-class clinical pain services, provides education on all aspects of pain management, coordinates and conducts Institutional Review Board-approved clinical research and Institutional Animal Care and Use Committee-approved basic laboratory and translational pain research, and serves as the advisory organization for developing enterprise-wide pain policy for the Military Health System. In FY15, the Pain CoE funding line is transferred from Army to USUHS.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Pain Center of Excellence (Army)	0.937	2.888	-
Description: The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration.			
FY 2013 Accomplishments: The Pain Center of Excellence reviewed data collected from approved FY11-12 protocols, and the center wrote general management and/or general practice guidelines that can be utilized in treating acute and chronic pain. Findings were communicated to the tri-services as well as the Veterans Health Administration in an effort to standardize pain management across agencies. Established protocols were continued with data collection and evaluation. Proposed protocols obtained Institutional Review Board approval and began data collection.			
FY 2014 Plans: The Pain Center of Excellence members of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) continues to validate major lines of effort including the Defense and Veterans Pain Rating Scale (DVPRS), Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcome Measurement Information System (PASTOR/PROMIS), and Extension for Community Healthcare Outcomes (ECHO) programs. DVCIPM continues to explore pain management therapeutic options to develop and optimize best practice guidelines for the treatment of pain. The research program focuses on evaluation of current medications for improved pain management, clinical assimilation study of integrative medicine modalities including yoga and acupuncture, and exploration of the pathophysiology (study of functional changes associated with disease or injury)			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 382A / *CoE-Pain Center of Excellence (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
and molecular mechanisms of pain with established and new academic partners. DVCIPM continues to provide subject matter expertise, coordination, and guidance to all services and Veterans Health Administration regarding pain-related issues in support of the Pain Task Force. ***FY 2015 Plans:*** No funding programmed. Program transfered to USUHS starting in FY 2015.			
Accomplishments/Planned Programs Subtotals	0.937	2.888	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

Performance by the Pain Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 382B / *CoE-Pain Center of Excellence (USUHS)*	

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
382B: *CoE-Pain Center of Excellence (USUHS)*	-	-	-	2.722	-	2.722	2.823	2.871	3.247	2.810	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

The Pain Center of Excellence (Army) examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration. The Pain Center of Excellence is an integral part of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) whose mission is to become a referral center that supports world-class clinical pain services, provides education on all aspects of pain management, coordinates and conducts Institutional Review Board-approved clinical research and Institutional Animal Care and Use Committee-approved basic laboratory and translational pain research, and serves as the advisory organization for developing enterprise-wide pain policy for the Military Health System. In FY15, the Pain CoE funding line is transferred from Army to USUHS.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Pain Center of Excellence (USUHS)	-	-	2.722

Description: The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration.

FY 2013 Accomplishments:
No funding programmed.

FY 2014 Plans:
No funding programmed.

FY 2015 Plans:
The Uniformed Services University of the Health Sciences (USUHS) will assume the research work of the DVCIPM beginning in FY 2015. The Pain Center of Excellence members of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) will continue to validate major lines of effort including the Defense and Veterans Pain Rating Scale (DVPRS), Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcome Measurement Information System (PASTOR/PROMIS), and Extension for Community Healthcare Outcomes (ECHO) programs. DVCIPM will continue to explore pain management therapeutic options to develop and optimize best practice guidelines for the treatment of pain. The research program will focus on evaluation of current medications for improved pain management, clinical assimilation study of integrative medicine modalities including yoga and acupuncture, and exploration of the pathophysiology (functional change) and molecular

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 382B / *CoE-Pain Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
mechanisms of pain with established and new academic partners. DVCIPM will provide subject matter expertise, coordination, and guidance to all services and Veterans Health Administration regarding pain-related issues in support of the Pain Task Force.			
Accomplishments/Planned Programs Subtotals	-	-	2.722

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

Performance by the Pain Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*	

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
383A: *CoE-Prostate Cancer Center of Excellence (USUHS)*	7.164	6.352	8.061	6.907	-	6.907	6.260	5.456	4.628	1.887	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USUHS), the Prostate Cancer Center of Excellence (CoE), formerly a Congressional Special Interest program, the Center for Prostate Disease Research (CPDR), was chartered in 1992 to conduct basic, clinical and translational research programs to combat diseases of the prostate. The CPDR studies prostate cancer and prostate diseases in the military health care system. The program's mission is fulfilled primarily through its three principal programs- the Clinical Translational Research, the Basic Science Research and the Tri-Service Multicenter Database which includes five participating military medical centers. The CPDR has been conducting patient centric cutting-edge translational research to improve the management of all stages of prostate cancer for over 22 yrs as recognized by nearly 400 scientific publications. CPDR has also been committed to the research training of the next generation of DoD doctors and scientists (USU medical and graduate students and Walter Reed residents). Many of the trainees are now service chiefs and program directors in prestigious military and civilian medical centers.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: CoE-Prostate Cancer Center of Excellence (USUHS)	6.352	8.061	6.907

Description: The CPDR is at the forefront of cutting-edge clinical research improving diagnosis and treatment of prostate cancer involving new modalities such as, MRI guided biopsy, and evaluation of new drugs and vaccines for advanced prostate cancer. The CPDR Database continues to highlight emerging issues in prostate cancer management such as, treatment outcomes, ethnic differences and quality of life. In light of current treatment challenges with early detected prostate cancers in PSA testing era and poorly understood biology of prostate cancer, CPDR's high-impact research is focusing on cancer causing genes that will lead to better diagnostic and prognostic markers in the management of the disease. New gene discoveries are also unraveling ethnic differences of prostate cancer biology that has potential to enhance personalized medicine.

FY 2013 Accomplishments:

- A highly motivated clinical research team offers unique opportunities for translational research and innovative clinical trials in an expedient manner.
- The CPDR Clinical Research Center, within the John P. Murtha Cancer Center at Walter Reed National Military Medical Center provides state-of-the-art care to military beneficiary patients affected by prostate disease, with particular emphasis on cutting-edge clinical trials.
- The clinical center maintains a clinical trial portfolio treating all stages of prostate cancer from prevention to late stage disease including the collaboration with the NCI Medical Oncologists.

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
• CPDR continues to lead its original discovery towards evaluations of a common defect of ERG cancer gene in prostate cancer diagnosis, prognosis and treatment. Development of the CPDR-ERG monoclonal antibody has streamlined the world-wide evaluations of the ERG oncoprotein in clinical specimens. • New ground-breaking research from CPDR has established unexpected ethnic differences of ERG frequencies between Caucasian Americans and African American patients. These results for the first time have potential to define molecular basis of ethnic differences in prostate cancer which has implications in both the fields of biomarker performance and personalized medicine. • A new CPDR initiative has led to the generation of whole-genome and transcriptome data in a matched cohort of African American and Caucasian American patients that is anticipated to enhance the understanding of genomic differences of prostate cancer between these ethnic groups. • Cancer biology evaluation of the most common prostate cancer gene ERG in transgenic mouse model has provided new insights into the mechanisms of ERG functions in prostate cancer initiation and progression. • Towards developing innovative prostate cancer diagnosis and prognosis platforms, collaborations are in progress with leading companies such as, Genomic Health, Iris Molecular Diagnostics, Berg Pharma, Biocare Medical and Exosome. • Hormonal mechanisms play central roles in prostate cancer onset of progression. CPDR has developed a new marker panel to read out the defects of hormone pathways in subsets of prostate cancers that may represent highly aggressive disease. CPDR has also made a discovery of a new pathway for androgen receptor degradation which has future potential in treatment of advanced prostate cancer. • The National Database program continues to enroll men with prostatic diseases including clinico-pathologic, demographic, and longitudinal follow-up and treatment outcomes data. • A new collaborative initiative has been established to evaluate the utility of a prognostic Oncotype DX prostate cancer panel developed by Genomic Heath. • The Biospecimen Banking and Database programs continue to enhance multi-disciplinary translational research activities at CPDR and other leading DoD and civilian medical centers. • The Integrated CPDR Information Management System has been completed that includes integration of bio-medical data, controlled biospecimen management and tracking systems. • In FY13, the Prostate Cancer CoE published 15 peer-reviewed publications and 3 invited articles. In addition, researchers at the Prostate Cancer CoE presented 6 podium presentations and 27 poster presentations at major national and international conferences. • Within the Education Program, CPDR scientific staff personnel continued the training of urology residents from WRNMMC, USU medical and graduate students, International Urologic Oncology fellows, Georgetown University medical students, CPDR postdoctoral fellows, NCI-Cancer Prevention postdoctoral fellow and CPDR Summer Interns.			
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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
• Evaluate the efficacy of the newly developed MRI guided biopsy technology in the diagnosis of clinically significant prostate cancer. • Assess new FDA approved drugs and vaccines for the treatment of the metastatic disease. • Investigate minimally invasive modalities for the treatment of early detected prostate cancer. • Analyze the features of onset and progression of prostate cancer among DoD prostate disease patients in relation to ethnicity and obesity. • Complete a new collaborative study with Genomic Health towards the evaluation of early prognostic gene expression markers for differentiating indolent versus aggressive disease. • Using the CPDR ERG-MAb, continue to enhance the ERG-based stratification of prostate cancer world-wide in collaboration with Biocare Medical Inc. • Complete the evaluation of ERG oncoprotein frequency in patient populations of China, Germany, Hungary, Japan, India, Malaysia, Philippines and Switzerland. • Develop and enhance strategies to inhibit ERG-mediated oncogenesis using small molecule inhibitors, ERG-MAb and ERG vaccine. • Complete the integrated comparative evaluations of genomics and transcriptomics (expression level of RNA molecules in a given cell population) datasets of African American and Caucasian American patients. • Accelerate prostate cancer-related genome queries by acquiring high-throughput technologies to support advanced bioinformatics capabilities. • Provide solution for the unmet need of prognostic biomarkers that will differentiate between indolent and aggressive disease. Evaluate the NanoString platform towards this goal. • Enhance the CPDR discovery of male hormone signaling-based stratification of prostate cancer, conceptually similar to breast cancer. • Define new mechanisms of male hormone receptor regulation towards developing innovative therapeutic strategies. • Improve non-invasive approaches for the detection of prostate cancer in urine or blood specimens by evaluating prostate cancer antigens, as well as auto-antibodies. • Continue to enhance and transform Prostate Cancer COE database and biospecimen banks to a national center for academic and industrial collaborations to accelerate translational research			
FY 2015 Plans: • Continue to conduct long-term comparisons of efficacy, morbidity, mortality and quality-of-life impact for accepted and emerging treatments for prostate cancer to include robot assisted radical prostatectomy, external beam radiotherapy, brachytherapy, high intensity focused ultrasound, and active surveillance. Assess the impact of these treatments with or without neoadjuvant and adjuvant hormonal or other novel therapies. • Compare the features of disease onset and progression between DoD and civilian prostate cancer patient populations.			

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 383A / *CoE-Prostate Cancer Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
• Continue focus on long-term studies of the epidemiology to include clinical progression of the disease defined by metastasis, ethnicity, obesity, quality-of-life-adjusted survival and prostate cancer specific death. • Evaluate traditional and emerging molecular marker panels for differentiating indolent versus aggressive disease for guiding treatment decisions. • Leverage the CPDR discovery of the ETS-related gene (ERG), the first major prostate cancer-causing gene identified, which is present in over half of prostate cancers in Western countries, and can be used for precision diagnosis and therapy. • Develop new molecular strategies for improving prostate cancer diagnosis and prognosis, specifically to find replacement for PSA test. • Establish the molecular bases of ethnic differences in prostate cancer biology by employing integrated comparative genomics and transcriptomics. • Develop new paradigms for the identification and treatment of highly aggressive prostate cancers based on hormone signaling defects. • Continue to evaluate cancer biology of prostate cancer relevant genes and/or proteins using transgenic and knockout mice models. • Identify molecular determinants of prostate cancer susceptibility in high-risk groups such as African Americans. • Continue to develop and maintain long-term molecular specimen resources for translational investigations at CPDR and collaborations with other institutions. • Maintain the state-of-the-art CPDR translational research infrastructure and expertise to train the next generation of DoD physicians and scientists.			
Accomplishments/Planned Programs Subtotals	6.352	8.061	6.907

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Prostate Cancer Center of Excellence: Performance is judged on high impact discoveries, development of new diagnostic and treatment strategies, identification of emerging issues of disease feature and patterns, the amount of extramural funding received, the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of medical students, residents and post-doctoral fellows in the Military Health System.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 398A / *CoE-Neuroscience Center of Excellence (USUHS)*	

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
398A: *CoE-Neuroscience Center of Excellence (USUHS)*	1.822	-	1.926	-	-	-	-	-	-	-	-	-

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: CoE-Neuroscience Center of Excellence (USUHS)	-	1.926	-

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

FY 2013 Accomplishments:

The Neuroscience Center of Excellence funded six projects based on external peer review and AIBS scoring. Those studies are:
- Early QSART- Can it predict CRPS after traumatic peripheral nerve injury?
- Effects of caffeine and heat exposure on exercise induced creatine kinase
- An anti-inflammatory approach to diagnosis and treatment of combined PTSD and mild TBI
- Histone deacetylase (HDAC) inhibitors to rescue cognitive impairment in blast-induced mTBI
- Enhancement of endocannabinoid tone in traumatic brain injury
- Sildenafil for the treatment of cerebrovascular dysfunction during the chronic stage after traumatic brain injury.

FY 2014 Plans:

The MCNCoE will complete restructuring of its vision and mission. This restructuring began in 2013 and continues into 2014, and includes re-codifying of the governance of MCNCoE, establishing a permanent external scientific advisory board (SAB). The MCNCoE will fund new clinical research projects through a call for proposals reviewed by SAB, and enhance the capability

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 398A / *CoE-Neuroscience Center of Excellence (USUHS)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
of MCNCoE to involve clinical neuroscientists across the DoD and at affiliated civilian academic centers in collaborative work with MCNCoE. Plans include involvement of national and international research leaders in the field of neurology from national capital area as well as across military healthcare system. Mission will also refocus on promoting education and training of military medical students, residents, fellows and staff in clinical neuroscience standards of care, outcome measures, and research initiatives with a focus on military-specific neurological conditions. With three ACGME accredited joint (tri-service) Military Neurology training programs in the DoD affiliated with USUHS Neurology, restructuring will include evaluating and augmenting clinical residency research opportunities in neurological disorders seen in military beneficiaries to include co-occurring conditions of special interest such as traumatic brain injury, neurodegenerative conditions, post-traumatic headaches, depression, chronic pain, epilepsy, nerve injury, post-traumatic stress disorders, and other clinical conditions that impact on full recovery. In sync with the President's call for Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, MCNCoE is poised to leverage military neuroscience clinicians at USUHS, in the national capital area, across the DoD Military Treatment Facilities, and with MTF academic affiliates to augment the understanding of human brain function which the President has established as an “enormous mystery waiting to be unlocked” (April 2013). ***FY 2015 Plans:*** None, MCNCoE research has been merged into the CNRM beginning in FY 2015.			
Accomplishments/Planned Programs Subtotals	-	1.926	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance of individual PIs will be judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the amount of extramural funding received. Performance of the overall program will be also measured on the effective achievement of better communication and research collaborations between neurology researchers across the DOD system, and on the ability of the Program to affect improvements to the academic curriculum at USUHS.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 429A / *Hard Body Armor Testing (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
429A: *Hard Body Armor Testing (Army)*	0.813	0.543	-	-	-	-	-	-	-	-	-	-

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Hard Body Armor	0.543	-	-
Description: Develop a surface-mounted sensor system that will add critical dynamic data to the current clay test procedure and develops human skull fracture injury criteria for focused blunt impacts to the human head. ***FY 2013 Accomplishments:*** The Hard Body Armor project conducted validation of the performance of the surface mounted clay add-on device using live-fire tests of military grade armor systems. This will provide the first bio-medically valid behind-body-armor design standard allowing equipment developers to design body armor appropriate to the specific needs of each region of the body. Also, the Hard Body Armor project tested the probability of skull fracture in relation to measured injury metrics such as head acceleration load. The development of a body armor surface sensor working prototype was initiated. In addition, head injury prediction simulations were conducted to associate observed skull fractures with well-defined loading/injury scenarios. ***FY 2014 Plans:*** No funding is programmed. ***FY 2015 Plans:*** No funding is programmed.			
Accomplishments/Planned Programs Subtotals	0.543	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 429A / *Hard Body Armor Testing (Army)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

Principal investigators will participate in In-Progress Reviews, DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and/or are subjected to Program Sponsor Representative progress review to ensure that milestones are being met and deliverables will be transitioned on schedule.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 431A / *Underbody Blast Testing (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
431A: *Underbody Blast Testing (Army)*	14.544	6.385	11.289	4.818	-	4.818	2.679	1.869	-	-	-	-

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Underbody Blast Testing	6.385	11.289	4.818
Description: Will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or IED, and will provide the biomedical basis for the development of a Warrior-representative blast test manikin and associated biomedically-validated injury criteria that can be used to characterize dynamic events and injury risks for live-fire test and evaluation (LFT&E) crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats.			
FY 2013 Accomplishments: The Underbody Blast Testing project collected human response data in a blast environment, including whole-body kinematics (measurement of motion), biofidelity data, and injury data for a seated soldier. This included fabricating and proof testing a first-of-its-kind blast experimental facility for medical research and the associated research techniques. The research considered the effects of warrior posture, the effects of wearing personal protective equipment, and the severity of the UBB threat. Matched pair testing clearly demonstrated differences between the current manikin and actual human response. Research results were coordinated with the Armed Forces Medical Examiner System and demonstrated that the observed injuries closely matched those experienced by soldiers in theaters of operation. A report was received and the data was transitioned for use in development 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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 431A / *Underbody Blast Testing (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
the new WIAMan anthropomorphic test device, to inform plans for subsequent research, and for use in modeling and simulation studies. Research plan reviews and test readiness reviews were conducted to define and approve subsequent research for whole-bodies and within particular body regions. Initial research was conducted for the head and neck body region to gather biofidelity and injury data. In addition, a first of its kind review was held to present the medical researchers with de-identified medical images of soldier injuries caused by UBB. This data is critical to assuring that the Underbody Blast Testing project is producing data that is relevant to the military environment. ***FY 2014 Plans:*** The Underbody Blast Testing project will be focused on generating and providing medical research data needed to support the development of the WIAMan anthropomorphic (resembling a human) test device concept and the first generation prototype. The emphasis will be on non-injurious or biofidelity data but will also include injurious testing. All body regions will be addressed including whole-body testing and also prioritized testing of the following body regions, foot and ankle, leg, pelvis, lumbar spine, thoracic spine, cervical spine, torso, head and neck. Medical research is adding variations in boundary conditions and other initial condition, including the effect of personal protective equipment. Conduct studies to contrast injuries observed in theater with those created in the test program to validate and prioritize research. Emerging medical research data will be disseminated to the RDT&E community to support protection technology development and modeling and simulation initiatives. ***FY 2015 Plans:*** The Underbody Blast Testing project will continue medical research in the areas initiated in FY14 but with the emphasis shifting during the year from non-injurious conditions to those which cause injuries. This will enable the development of initial human injury probability curves that account for influences unique to the military and UBB environment. All data will continue to be transitioned into the WIAMan project to enable the fabrication of the first and second generation prototype anthropometric test devices (ATDs). Continue studies to contrast injuries observed in theater with those created in the test program to validate and prioritize research. Emerging medical research data will be disseminated to the RDT&E community to support protection technology development and modeling and simulation initiatives. Work will be initiated to prepare to perform matched pair testing of the first generation WIAMan prototype.			
Accomplishments/Planned Programs Subtotals	6.385	11.289	4.818

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 431A / *Underbody Blast Testing (Army)*

D. Acquisition Strategy

Produce biofidelity response corridors (BRC) and human injury probability curves (HIPC) for human skeletal response and tolerance in the military UBB environment and transition them for use in the development of the WIAMan UBB test manikin and for general use in the RDT&E community. Develop injury assessment reference curves for use with WIAMan manikin to support vehicle and protection technology acquisition decisions.

E. Performance Metrics

Performance metrics include the timely transition of actionable medical research from principal investigators for use in the development of the WIAMan UBB test manikin and to benefit the RDT&E protection technology and acquisition community. Actionable medical research includes biofidelty response corridors (BRCs), human injury probability curves (HIPC), and injury assessment reference curves (IARCs). Principal investigators will participate in In-Progress Reviews, technical interchange meetings, and theater injury analysis reviews. PIs will publish emerging results in the proceedings of injury biomechanics symposia and in relevant journals. As required, PIs will participate in DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and are subjected to Program Sponsor Representative progress review to ensure that milestones are being met and deliverables will be transitioned on schedule. An external peer review of the medical research will be conducted to ensure the medical research is scientifically valid and suitable for accreditation for use in supporting acquisition decisions.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 448A / *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
448A: *Military HIV Research Program (Army)*	-	-	6.912	5.773	-	5.773	6.589	6.701	7.579	5.792	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Military HIV Research Program	-	6.912	5.773
Description: The Military HIV Research Program aims to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. ***FY 2013 Accomplishments:*** No DHP funding programmed. ***FY 2014 Plans:*** The Military HIV Research Program conducts safety and effectiveness studies with a combination vaccine in human volunteers at clinical trial sites world-wide and down-selects best candidates for further testing in human volunteers to study the ability of HIV vaccine candidates to provoke an immune response that can protect against HIV. ***FY 2015 Plans:*** Will conduct initial testing in humans for safety and effectiveness at CONUS and OCONUS sites with HIV-1 multivalent vaccine candidates. Initiate large scale production of vaccine candidates from various world-wide subtypes. These candidates will be used in future large scale clinical studies.			
Accomplishments/Planned Programs Subtotals	-	6.912	5.773

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 448A / *Military HIV Research Program (Army)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Mature and demonstrate candidate HIV vaccines, prepare and conduct human clinical studies to assess safety and effectiveness of candidate HIV vaccines. All HIV technology development activities are conducted in compliance with FDA regulations. Best selected candidates will be transitioned to advanced development through Milestone B.

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.

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 0603115HP / *Medical Technology Development*	Project (Number/Name) 830A / *Deployed Warfighter Protection (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
830A: *Deployed Warfighter Protection (Army)*	5.077	3.924	5.420	4.553	-	4.553	5.306	5.397	6.105	4.666	Continuing	Continuing

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

A. Mission Description and Budget Item Justification

For the Armed Forces Pest Management Board (AFPMB), the Deployed Warfighter Protection project plans to develop new or improved protection for ground forces from disease-carrying insects. The focus of this program is to develop new or improved systems for controlling insects that carry disease under austere, remote, and combat conditions; understand the physiology of insecticidal activity to develop new compounds with greater specific activity and/or higher user acceptability; examine existing area repellents for efficacy and develop new spatially effective repellent systems useful in military situations; develop new methods or formulations for treating cloth to prevent vector biting; and expand the number of active ingredients and formulations of public health pest pesticides, products and application technologies available for safe, and effective applications.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Deployed Warfighter Protection	3.924	5.420	4.553

Description: The Deployed Warfighter Protection Program will develop new or improved protection for ground forces from disease-carrying insects.

FY 2013 Accomplishments:

The Deployed Warfighter Protection research project expanded and continued implementing plans from FY12 to include new and improved control methods for mosquitoes, sand flies, filth flies and other insects of military importance; assessing innovative spray equipment and conducting pesticide efficacy trials in desert, temperate and tropical environments. This included refocusing control strategies for mosquitoes and sand flies, which are considered the main disease-bearing insect threats to deployed forces; new insect repellent systems and the modification of insecticide application technologies that are more effectively targeting disease carrying insects impacting military readiness. DWFP funded research efforts conducted by the US Department of Agriculture (USDA) Agricultural Research Service were featured in the November/December 2012 edition of the USDA ARS Magazine (See: http://www.ars.usda.gov/is/AR/archive/nov12/index.htm). The article provided an overview of the DoD funded research conducted by the USDA ARS highlighting synergistic efforts specifically meeting the needs of the military and notable for having an exceptional return on investment ratio of approximately 3 dollars of research effort for every 1 DWFP dollar invested. Similar successes were achieved in the competitive grant portfolio where DWFP managed 15 grants given to industry, academia and government labs in FY13. So far in FY13 DWFP produced an additional market-ready product and several more expected in the coming months. Specifically, attractive targeted sugar bait (ATSB®) received a registered trademark, patented use, commercial partner and Environmental Protection Agency (EPA)-approved label for the professional product being evaluated for

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 830A / *Deployed Warfighter Protection (Army)*

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

efficacy in mosquito control districts throughout CONUS and against sand flies in Europe. Feedback from these trials will impact the final military use product. Other significant accomplishments included several material transfer agreements with both US and international companies to evaluate and develop products used around the globe for insect protection, but not currently available in the US. These included spatial / area repellents; a critical replacement for permethrin treatment of military uniforms to make them repellent against biting insects; new specialized spray products for treating aircraft and ships; and durable insecticidal lining materials for attaching to interior walls of tents and more permanent structures. Significant advances were also made toward commercial development of an additional pesticide active ingredient for use as a rodent feed-through insecticide for killing desert sand flies that transmit human disease to military personnel. Numerous commercially available and experimental insecticides and sprayers were evaluated with the best performers added to the military stock system for use by combat forces. Two US patents were issued and seven submitted for products with military utility. These comprised the ATSB method; two new spatial repellents; a topical repellent more potent and longer-lasting than the common DEET; insecticide curtains for keeping insects out of aircraft and ships; specialized formulation of a toxicant (poison that is made by humans) used in a DWFP patented mosquito trap; a skin applied product that prevents insects from detecting human odors; an atomizer to produce ultra small droplets needed to kill flying mosquitoes; and a new bed net fabric design. Arising from the cumulative DWFP efforts on sand fly control, AFPMB approved the addition of a DoD technical guide for sand fly biology and control globally. During FY13, more than 70 additional peer reviewed scientific publications resulted from DWFP efforts. New and ongoing efforts are detailed in the FY14 section below. Multiple USDA and Competitive Grant projects were delayed by 3 to 6 months due to reduced funding for FY13.

FY 2014 Plans:

The Deployed Warfighter Protection project continues FY13 efforts concentrating on developing products and resources to enable combat forces to better protect themselves and control militarily important insects that bite, sting and transmit force degrading diseases. This is accomplished through continuing R&D to discover, develop, patent, license, produce and secure commercially feasible products, and EPA registration of new and improved insecticides, application technologies and repellent systems. The DWFP is: (1) actively pursuing EPA product label changes for use against disease-carrying insects threatening deployments outside the United States; (2) continuing field trials, engaging regional, national and international commercial partners and developing reduced risk pesticides such as ATSBs® and other insecticides found to be effective for desert sand flies, blood-sucking flies and filth fly control; (3) continuing cooperative work and formal Agreements with industry promoting insecticide development and EPA registrations; (4) evaluating insect control materials and application technologies in collaboration with military labs and others in Africa, Asia, Europe and the Pacific; (5) conducting field trials of patented next generation “lethal ovitraps” designed to attract and kill disease carrying mosquitoes when they are trying to lay their eggs; (6) optimizing patented molecular, highly specific insecticides based on genes specific for target insects; (7) continuing field evaluations of experimental and military stock listed equipment and insecticides against CONUS and OCONUS medically important insects; (8) continuing evaluations of new commercial sprayers, with best performing products added to the military stock system; (9) continuing assessments of how insecticide aerosols kill insects in desert, temperate and tropical environments; (10) continuing CONUS

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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 830A / *Deployed Warfighter Protection (Army)*

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

and OCONUS evaluations of spatial repellents and insecticides used as barriers for sand flies and other medically important arthropods; (11) evaluating prototype hybrid insecticide sprayers that use the best attributes of existing technologies; (12) continuing to develop and evaluate effectiveness of new and existing insecticide treated military uniforms, finding supplementary or replacement compounds for future use; (13) continuing to validate efficacy of military issue repellents against insects that are infected with disease causing pathogens; (14) conducting field evaluations of military uniform attachments impregnated with volatile insecticides to kill and repel insects; (15) continuing to identify sensory structures on mosquitoes that detect DEET and other repellent active ingredients, basic findings that can lead to custom blends and molecular designs of new repellents; (16) continuing to screen and develop plant-derived insecticides and repellents with high potential for military use; (17) continuing to develop and field new insecticides and improved formulations to treat military uniforms and other military textiles used in a variety of climates; (18) developing and fielding new stock-listed insecticide sprayers including electro-static technologies; and, (19) continuing to synthesize and screen new compounds for insecticidal and repellency properties. Given FY13 funding levels, the Program did not issue a request for proposals as part of the Competitive Grant program for new FY14 starts.

FY 2015 Plans:

The Deployed Warfighter Protection (DWFP) project will continue to develop and field tools that enable deployed forces to better protect themselves and control militarily important insects that bite, sting and transmit force degrading diseases. This will be accomplished through continued research, testing and evaluation, patent submissions, licensing, and EPA registrations for new insecticides, application technologies and repellent systems. DWFP will prioritize research efforts that focus on critical gaps identified by the Services and Combatant Commands to control insects (mosquitoes, sand flies, fleas, flies, mites, and ticks) and provide tools in 3 thrust areas: personal protection systems, insecticides and application technologies. Focus areas which will continue for FY15 include:

• Enhanced Personal Protection Systems: Transition prototype bite-proof fabrics from the lab to initial field testing; continue safety, efficacy, user acceptability and durability studies of combat uniforms treated with a new chemical to replace permethrin; and transition lab prototype micro-dispensers and textile-based area/spatial-repellent dispensers for arthropod repellent/toxicants to initial field tests.

• New Insecticides: Work with the EPA to pursue EPA product label changes for use against disease-carrying insects threatening deployments outside the United States; continue FY14 collaborations and formal agreements with industry partners to develop new insecticides for EPA registration; initiate semi-field testing of molecular pesticides that attack specific genes in the insect and new essential oil insecticides and synergists; continue studies to determine how insecticides kill insects in order to support development of improved insect control technologies effective in desert, temperate and tropical environments; and continue screening efforts to evaluate plant-derived and other natural insect control compound with improved safety profiles and high potential for military use.

• Next generation Application Technology: Conduct initial field testing of next generation portable insecticide sprayers including electro-static technologies and other emerging technologies to field lighter systems; develop smart phone based applications 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 0603115HP / *Medical Technology Development*	**Project (Number/Name)** 830A / *Deployed Warfighter Protection (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
support decision makers and field, insect control operators; transition patented attractive targeted sugar bait delivery technology to a commercial partner as a novel reduced risk pesticide.			
Accomplishments/Planned Programs Subtotals	3.924	5.420	4.553

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Develop, mature and field new or improved products and strategies that protect US forces from disease-carrying insects. Secure registered trademarks, patents, commercial partners, and/or EPA registration of new or improved insecticides, application technologies and repellent systems. Continue to partner with industry to field products and coordinate with the Services and relevant Program Executive Offices (PEOs) to transition efforts.

E. Performance Metrics

Performance for the Deployed Warfighter Protection Program is measured by the insecticides and other products given EPA registration and added to the military stock system, changes in pest management techniques or technologies used by the military to control biting/disease causing insects, patents, and peer-reviewed scientific manuscripts. The Program conducts an annual Research Review during which a panel of DoD subject matter experts provides input on programmatic alignment and strategic priorities.