Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Army											Date: February 2015	
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 3: *Advanced Technology Development (ATD)*					R-1 Program Element (Number/Name) PE 0603002A *I Medical Advanced Technology*							
COST ($ in Millions)	**Prior Years**	**FY 2014**	**FY 2015**	**FY 2016 Base**	**FY 2016 OCO**	**FY 2016 Total**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**Cost To Complete**	**Total Cost**
Total Program Element	-	100.646	106.264	69.584	-	69.584	68.365	70.847	71.919	73.341	-	-
810: *Ind Base Id Vacc&Drug*	-	17.096	18.269	18.719	-	18.719	16.696	17.889	18.052	18.406	-	-
814: *NEUROFIBROMATOSIS*	-	15.000	15.000	-	-	-	-	-	-	-	-	-
840: *Combat Injury Mgmt*	-	30.633	29.321	30.572	-	30.572	31.189	32.247	32.798	33.448	-	-
945: *BREAST CANCER STAMP PROCEEDS*	-	0.497	-	-	-	-	-	-	-	-	-	-
97T: *NEUROTOXIN EXPOSURE TREATMENT*	-	16.000	16.000	-	-	-	-	-	-	-	-	-
FH4: *Force Health Protection - Adv Tech Dev*	-	1.606	1.691	1.268	-	1.268	1.332	1.776	1.868	1.905	-	-
MM2: *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*	-	8.000	8.000	-	-	-	-	-	-	-	-	-
MM3: *Warfighter Medical Protection & Performance*	-	11.814	17.983	19.025	-	19.025	19.148	18.935	19.201	19.582	-	-

A. Mission Description and Budget Item Justification

This program element (PE) maturates and demonstrates advanced medical technologies including drugs, vaccines, medical devices, diagnostics, and developing medical practices and procedures to effectively protect and improve the survivability of U.S. Forces across the entire spectrum of military operations. Cross DoD coordinated and cooperative efforts are focused in four principal medical areas: Combat Casualty Care, Military Operational Medicine, Militarily Relevant Infectious Diseases, and Clinical and Rehabilitative Medicine.

Promising medical technologies are refined and validated through extensive testing, which is closely monitored by the U.S. Food and Drug Administration (FDA) and Environmental Protection Agency (EPA), as part of their processes for licensing and/or approving new medical products. The FDA requires medical products to undergo extensive preclinical testing in animals and/or other models to obtain preliminary effectiveness and safety information before they can be tested in human clinical trials. Clinical trials are conducted in three phases to prove the safety of a drug, vaccine, or device for the targeted disease or medical condition, starting in Phase 1 with a small number of healthy volunteers. Following Phase 1, Phase 2 clinical trials to provide expanded safety data and evaluate the effectiveness of a drug, vaccine, or medical device in a larger population of patients having the targeted disease or medical condition. Each successive phase includes larger numbers of human subjects and requires FDA cognizance prior to proceeding. Work conducted in this PE primarily focuses on late stages of technology maturation activities required to conduct Phase 1 and 2 clinical trials. Some high-risk technologies may require additional maturation with FDA guidance prior to initiating these clinical trials. Such things as proof of product stability and purity are necessary to meet FDA standards before entering later stages of testing and prior to transitioning into a formal acquisition program

where large Phase 3 pivotal trials will be conducted for licensure. Activities in this PE may include completion of preclinical animal studies and Phase 1 and 2 clinical studies involving human subjects according to FDA and EPA requirements. Promising medical technologies that are not regulated by the FDA are modeled, prototyped, and tested in relevant environments.

Blast research and research into maturing field rations in this PE are fully coordinated with the United States Army Natick Soldier Research, Development, and Engineering Center. This coordination enables improved body armor design and rations for Soldiers. Additionally, the activities funded in this PE are externally peer reviewed and fully coordinated with all Services as well as other agencies through the Joint Technology Coordinating Groups of the Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (COI). The ASBREM COI, formed under the authority of the Assistant Secretary of Defense for Research and Engineering, serves to facilitate coordination and prevent unnecessary duplication of effort within the Department of Defense's biomedical research and development community, as well as its associated enabling research areas.

Project 810 maturates and demonstrates FDA-regulated medical countermeasures such as drugs, vaccines, and diagnostic systems to naturally occurring infectious diseases and wound infections of military importance, as identified by worldwide medical surveillance and military threat analysis. The project also supports testing of personal protective measures such as repellents and insecticides regulated by the EPA. This project is being coordinated with the Defense Health Program.

Project 840 validates studies on safety and effectiveness of drugs, biologics (products derived from living organisms), medical devices, and medical procedures intended to minimize immediate and long-term effects from battlefield injuries; advanced technology development and clinical studies for treatment of ocular (and visual system traumatic injury; and restoration of function and appearance by regenerating skin, muscle, and bone tissue in battle-injured casualties. Additionally, this project develops and realistically tests improved occupant protection systems through medical research to characterize mechanisms of injuries sustained by occupants of ground-combat vehicles subjected to underbody blast events, determine human tolerance limits to underbody blast forces, and develop tools to predict injuries to ground-combat vehicle occupants exposed to underbody blast forces.

Project FH4 maturates, validates, and supports enhanced Force Health Protection of Soldiers against threats in military operations and training. Health-monitoring tools are matured to rapidly identify deployment stressors that affect the health of Joint Forces. These databases and systems enhance the DoDs ability to monitor and protect against adverse changes in health, especially mental health effects caused by changes in brain function. Force Health Protection work is conducted in close coordination with the Department of Veterans Affairs. The program is maturing the development of global health monitoring (e.g., development of neuropsychological evaluation methodologies), validating clinical signs and symptoms correlating to medical records, diagnosed diseases, and mortality rates. The key databases supporting this program are the Millennium Cohort Study and the Total Army Injury and Health Outcomes Database. These databases allow for the examination of interactions of psychological stress and other deployment and occupational stressors that affect Warfighter health behaviors.

Project MM3 supports the Medical and Survivability technology areas with laboratory validation studies and field demonstrations of biomedical products designed to counteract myriad environmental and physiological stressors, as well as materiel hazards encountered in training and operational environments to protect, sustain, and enhance Soldier performance. The key efforts are to demonstrate and transition technologies, as well as validate tools associated with Soldier survivability, injury assessment and prediction, assessments for post-concussive syndrome, and enhancing performance during continuous operations. The three main thrust areas are

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Army	Date: February 2015
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 3: *Advanced Technology Development (ATD)*	**R-1 Program Element (Number/Name)** PE 0603002A *I Medical Advanced Technology*

(1) Physiological Health and Environmental Protection, (2) Injury Prevention and Reduction, and (3) Psychological Health and Resilience. This project contains no duplication with any effort within the Military Departments and includes direct participation by other Services.

Work funded in this project PE is fully coordinated with efforts undertaken in PE 0602787A and the Defense Health Program.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this PE is performed by Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD; U.S. Army Medical Research Institute of Infectious Diseases, Ft Detrick, MD; U.S. Army Research Institute of Environ. Med. (USARIEM), Natick, MA; U.S. Army Institute of Surgical Research, Ft Sam Houston, TX; U.S. Army Aeromedical Research Laboratory (USAARL), Ft Rucker, AL; the Naval Medical Research Center (NMRC), Silver Spring, MD; U.S. Army Dental Trauma Research Detachment (USADTRD), Ft. Sam Housto

B. Program Change Summary ($ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	100.999	67.291	70.050	-	70.050
Current President's Budget	100.646	106.264	69.584	-	69.584
Total Adjustments	-0.353	38.973	-0.466	-	-0.466
• Congressional General Reductions	-	-0.027			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	39.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	1.197	-			
• SBIR/STTR Transfer	-1.550	-			
• Adjustments to Budget Years	-	-	-0.466	-	-0.466

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2014	FY 2015
Project: 814: *NEUROFIBROMATOSIS*		
Congressional Add: *Neurofibromatosis Research Program*	15.000	15.000
Congressional Add Subtotals for Project: 814	15.000	15.000
Project: 945: *BREAST CANCER STAMP PROCEEDS*		
Congressional Add: *Breast Cancer Stamp Proceeds*	0.497	-
Congressional Add Subtotals for Project: 945	0.497	-

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Army	Date: February 2015
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Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2014	FY 2015
Project: 97T: *NEUROTOXIN EXPOSURE TREATMENT*		
Congressional Add: *Peer-Reviewed Neurotoxin Exposure Treatment Parkinsons Research Program*	16.000	16.000
Congressional Add Subtotals for Project: 97T	16.000	16.000
Project: MM2: *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*		
Congressional Add: *Military Burn Trauma Research Program*	8.000	8.000
Congressional Add Subtotals for Project: MM2	8.000	8.000
Congressional Add Totals for all Projects	39.497	39.000

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army			Date: February 2015
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) 810 / *Ind Base Id Vacc&Drug*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
810: *Ind Base Id Vacc&Drug*	-	17.096	18.269	18.719	-	18.719	16.696	17.889	18.052	18.406	-	-

A. Mission Description and Budget Item Justification

This project maturates and demonstrates U.S. Food and Drug Administration (FDA)-regulated medical countermeasures such as drugs, vaccines, and diagnostic (identification of the nature and cause of a particular disease) systems to naturally occurring infectious diseases that are threats to deployed U.S. military forces. The focus of the program is on prevention, diagnosis, and treatment of diseases that can adversely impact military mobilization, deployment, and operational effectiveness. Prior to licensure of a new drug or vaccine to treat or prevent disease, the FDA requires testing in human subjects. Studies are conducted stepwise: first to prove the product is safe in humans, second to demonstrate the desired effectiveness and optimal dosage (amount to be administered) in a small study, and third to demonstrate effectiveness in large, diverse human populations. All test results are submitted to the FDA for evaluation to ultimately obtain approval (licensure) for medical use. This project supports the studies for safety and effectiveness testing on small study groups after which they transition to the next phase of development for completion of expanded safety and initial studies for effectiveness in larger populations. If success is achieved for a product in this project, the effort will transition into Advanced Development. The project also supports testing of personal protective measures that can reduce disease transmission from arthropods to include products such as repellents and insecticides, which are regulated by the Environmental Protection Agency (EPA).

Research conducted in this project focuses on the following five areas:
(1) Drugs to Prevent/Treat Parasitic (organism living in or on another organism) Diseases
(2) Vaccines for Prevention of Malaria
(3) Bacterial Disease Threats (diseases caused by bacteria)
(4) Viral Disease Threats (diseases caused by viruses)
(5) Diagnostics and Disease Transmission Control

Research is conducted in compliance with FDA regulations for medical products for human use and EPA regulations for insect-control products that impact humans or the environment (e.g., repellents and insecticides).

Work is managed by Walter Reed Army Institute of Research (WRAIR) and the U.S. Army Medical Institute of Infectious Disease (USAMRIID) and coordinated with NMRC. The Army is responsible for programming and funding all Department of Defense (DoD) naturally occurring infectious disease research requirements, thereby precluding duplication of effort within the Military Departments.

Promising medical countermeasures identified in this project are further matured under PE 0603807A, project 808.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 810 / *Ind Base Id Vacc&Drug*

Work in this project is performed by the Walter Reed Army Institute of Research, Silver Spring, MD, and its overseas laboratories; USAMRIID, Fort Detrick, MD; and the Naval Medical Research Center (NMRC), Silver Spring, MD, and its overseas laboratories. Significant work is conducted under a cooperative agreement with the Henry M. Jackson Foundation, Bethesda, MD.

Efforts in this project support the Soldier portfolio and the principal area of Military Relevant Infectious Diseases.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Drugs to Prevent/Treat Parasitic Diseases	2.207	2.219	1.958
Description: This effort selects promising anti-parasitic drug candidates for treating malaria and leishmaniasis (a disease transmitted by sand flies) for testing in humans, prepares data packages required for FDA approval of testing in humans, and conducts that testing. Studies have shown that the malaria parasite can become resistant to existing drugs, which makes it necessary to continually research new and more effective treatments. ***FY 2014 Accomplishments:*** Assessed effectiveness of new and refined anti-parasitic drugs through testing in human populations exposed to malaria and leishmania infections world-wide. ***FY 2015 Plans:*** Advance new generation drugs with improved therapeutic index (largest dose producing no toxic symptoms) through small animal model testing. Perform clinical testing for safety and effectiveness of new selected candidate drugs and drug combinations. ***FY 2016 Plans:*** The down-selected compounds from Triazine group showing positive results in small animal testing in FY15 will be used in clinical testing for safety and effectiveness in human volunteers. Will also conduct clinical testing to assess metabolism (break-down within human body) of 8-aminoquinoline class drugs (i.e. primaquine) to improve drug safety and effectiveness for treatment and prevention of relapsing malarias (persons getting sick second time after drug treatment). Will transition best therapeutic (treatment or drug promoting disease healing) and preventive drug candidates to advanced development.			
Title: Vaccines for Prevention of Malaria	5.306	5.123	5.503
Description: This effort selects candidate vaccines for various types of malaria, including the severe form of malaria (Plasmodium falciparum) and the less severe but relapsing form (Plasmodium vivax), prepares technical data packages required for FDA approval of testing in humans and conducts testing of promising malaria vaccine candidates in humans. A malaria vaccine would minimize the progression and impact of drug resistance and poor Warfighter compliance with taking preventive anti-malarial drugs. ***FY 2014 Accomplishments:***			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 810 / *Ind Base Id Vacc&Drug*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Conducted human safety and effectiveness clinical trials of new formulations of vaccine candidates and assessed vaccine performance for suitability for transition to Advanced Development. ***FY 2015 Plans:*** Continue to conduct human safety and effectiveness clinical trials of new formulations of vaccine candidates supporting transition into Advanced Development. Conduct human clinical studies to assess how long malarial vaccination sustains protection levels. Down select lead P. falciparum vaccine candidates for transition into Advanced Development ***FY 2016 Plans:*** Will continue conducting human safety and effectiveness clinical trials of new formulations of vaccine candidates including weakened (so they do not produce disease) malaria sporozoites (infective stage of the parasite) in human volunteers to assess their safety and effectiveness. Will down-select the best vaccine candidate for transition to advanced development.			
Title: Bacterial Disease Threats ***Description:*** This effort selects promising candidate vaccines against each of the three main bacterial causes of diarrheas (E. coli, Campylobacter, and Shigella (a significant threat during initial deployments)) for testing in human subjects. Data packages are prepared, as required for FDA approval, and testing is conducted in human subjects. ***FY 2014 Accomplishments:*** Produced best vaccine candidates by using Good Manufacturing Practices developed by the FDA; conducted human (volunteers) safety trials of additional promising vaccine candidates against each of the three main bacterial causes of diarrhea. ***FY 2015 Plans:*** Conduct expanded vaccine candidate safety and effectiveness human clinical trials with two diarrheal pathogens, Shigella, and EnteroToxigenic E. coli (ETEC). Transition best successful down-selected vaccine candidates to Advanced Development. ***FY 2016 Plans:*** Will prepare data packages to present to the FDA for approval for human testing of vaccine candidates for bacterial diarrheal agents. Will conduct extended safety and effectiveness studies by using different escalating doses of down selected vaccine candidates against each of the three diarrheal agents (Shigella, ETEC and Campylobacter) in human volunteers. Will transition the best Shigella, ETEC & Campylobacter vaccine candidates, respectively, to Advanced Development.	5.179	4.916	4.518
Title: Viral Disease Threats ***Description:*** This effort progresses the most promising vaccine candidates against dengue fever (a severe debilitating disease caused by a virus and transmitted by a mosquito), and hantavirus (severe viral infection that causes internal bleeding and is contracted from close contact with rodents) and conducts FDA-required nonclinical safety and protection testing (laboratory-	2.703	4.886	5.116

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 810 / *Ind Base Id Vacc&Drug*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
based) in animals, prepare FDA investigational new drug technical data packages, and conducts clinical testing of candidate vaccines in humans. ***FY 2014 Accomplishments:*** Evaluated the alternative strategies to deliver vaccine candidates in human muscle and skin to develop a needle-free injection; explored the concept of using our DNA vaccines to produce antibodies that could be used to treat or prevent the diseases caused by hantaviruses; and further evaluated human safety and effectiveness of best vaccine candidates against all dengue types present worldwide. ***FY 2015 Plans:*** Complete clinical testing of selected hantavirus and dengue vaccine candidates for safety and initiate expanded clinical studies to test the efficacy of the candidate vaccine in human volunteers. Initiate expanded clinical testing for efficacy studies with multivalent dengue vaccine in US adults with new vaccine lots. Also initiate clinical studies for effectiveness in dengue endemic countries with best down-selected candidates. Refine the final vaccine formulation and delivery into human body. Initiate the development of a human challenge model for all four dengue viruses. Under this model, volunteers vaccinated with a dengue vaccine candidate are deliberately "challenged" with attenuated dengue viruses to assess whether or not the candidate vaccine can prevent dengue infection. ***FY 2016 Plans:*** Will conduct assessments of vaccine effectiveness and safety among human populations immunized with experimental dengue vaccines. Will continue development and testing of the experimental dengue human challenge model initiated in FY15. Will continue clinical trials with candidate DNA vaccine against hantaviruses and will continue to look for a commercial partner and a country where hantaviruses infections regularly occur, to conduct large scale clinical trials (FDA required). Will coordinate with the FDA to establish specific guidelines for the licensure of a hantavirus DNA vaccine.			
Title: Diagnostics and Disease Transmission Control ***Description:*** This effort conducts human subject testing of FDA-regulated field medical diagnostic devices and EPA-approved measures to control arthropods (i.e. insects, ticks & mites)-borne pathogens (infectious agents) that cause diseases such as Q fever, Sand fly fever, and Japanese encephalitis. ***FY 2014 Accomplishments:*** Initiated new field evaluations under the biosurveillance portion of the next-generation diagnostic system (NGDS) managed by Program Manager, Chemical Biologic Medical Systems, specifically for assays targeting vectors (organisms that transmit disease,	1.701	1.125	1.624

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 810 / *Ind Base Id Vacc&Drug*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
such as a mosquito) transmitting medically relevant diseases; conducted field evaluation of the new alternate repellent products in overseas field locations; and evaluated the NGDS assays (tests) for use in diagnosing pathogens (infectious agents) in humans. ***FY 2015 Plans:*** Develop Rapid Human Diagnostic Devices (RHDD) in collaboration with industry partners and transition to Advanced Development. WTest vector (organisms that transmit disease) surveillance devices in field. Test new vector control technologies with field applications and select best tools for military operations. ***FY 2016 Plans:*** Will support projects to research and develop RHDDs for priority diseases and pathogens (infectious agents) that are usable at or near the point of need. Will develop military relevant assays (i.e. panels differentiating diseases that have similar symptoms) to be transitioned for the next-generation diagnostic system (NGDS) platform. Will continue to test new vector control technologies in the field.			
Accomplishments/Planned Programs Subtotals	17.096	18.269	18.719

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army			Date: February 2015
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) 814 / *NEUROFIBROMATOSIS*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
814: *NEUROFIBROMATOSIS*	-	15.000	15.000	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Neurofibromatosis research.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
Congressional Add: Neurofibromatosis Research Program	15.000	15.000
FY 2014 Accomplishments: Neurofibromatosis Research Program		
FY 2015 Plans: Neurofibromatosis Research Program		
Congressional Adds Subtotals	15.000	15.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army			Date: February 2015
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) 840 / *Combat Injury Mgmt*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
840: *Combat Injury Mgmt*	-	30.633	29.321	30.572	-	30.572	31.189	32.247	32.798	33.448	-	-

A. Mission Description and Budget Item Justification

This project matures, demonstrates, and validates promising medical technologies and methods to include control of severe bleeding, treatment for traumatic brain injury (TBI), revival and stabilization of trauma patients, acute treatment of extremity (arms and legs) and facial injuries, treatment of severe burn wounds, treatment of single and multiple organ failures due to trauma, and predictive indicators and decision aids for life support systems. Post-evacuation medical research focuses on continued care and rehabilitative medicine for extremity, facial/maxillary (jaw bone), and ocular (eye) trauma and leveraging recent innovations in regenerative medicine and tissue engineering techniques.

Research conducted in this project focuses on the following six areas:

(1) Damage Control Resuscitation
(2) Combat Trauma Therapies
(3) Traumatic Brain Injury
(4) Combat Critical Care Engineering
(5) Clinical and Rehabilitative Medicine
(6) Underbody Blast Injury Assessment

All research is conducted in compliance with FDA requirements for licensure of medical products for human use.

Promising efforts identified through applied research conducted under PE 0602787A, project 874, are further matured under this project. Promising results identified under this project (840) are further matured under PE 0603807A, project 836.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this project is performed by the United States Army Dental & Trauma Research Detachment (USADTRD) and the U.S. Army Institute of Surgical Research (USAISR), Joint Base San Antonio-Fort Sam Houston, TX; the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD; and the Armed Forces Institute of Regenerative Medicine (AFIRM), Fort Detrick, MD.

Efforts in this project support the Soldier Portfolio and the principal areas of Combat Casualty Care and Military Operational Medicine.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 840 / *Combat Injury Mgmt*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Damage Control Resuscitation	6.916	6.953	7.200
Description: This effort supports work required to validate safety and effectiveness of drugs and medical procedures to control bleeding, maintain metabolism (the chemical processes that are required to maintain life) and minimize harmful inflammation after major trauma. Efforts focus on stopping bleeding, preserving tissue function and preventing or minimizing secondary organ failure (including brain and spinal cord injury). ***FY 2014 Accomplishments:*** Evaluated devices, biologics (medical products derived from living organisms), and techniques to control life-threatening internal bleeding caused by injuries to the chest and abdomen; continued studies of drugs and biologics to reduce inflammation as therapy for traumatic bleeding and developed laboratory assays and clinical practice guidelines for diagnosis of impaired blood clotting ability caused by trauma; and validated an improved blood platelet storage technology for far-forward use. ***FY 2015 Plans:*** Continue to evaluate hemostatic (acting to arrest bleeding or hemorrhage) medical products (drugs / devices) and techniques to control life threatening bleeding from areas of the body where tourniquets may not be effective such as within the chest and abdomen, and from large soft tissue (e.g. skin and muscle) injuries or injuries to the armpit or groin. Continue to evaluate drugs and biologics (medical products derived from living organisms) to reduce traumatic bleeding caused by inflammation. Conduct preliminary studies to help determine optimal conditions for extending platelet (a cell in blood that helps it clot) storage time and while also maintaining blood-clotting capability. These efforts support continued validation studies of novel blood platelet storage technologies for far-forward use. ***FY 2016 Plans:*** Will continue research from FY15 to evaluate hemostatic drugs, biologics, devices and techniques in relevant traumatic bleeding shock models. Extend FY15 work, will evaluate promising hemostatic devices designed to stop bleeding in body locations where tourniquets cannot be used; evaluations will be done in manikins and normal human volunteers. Will evaluate preclinical safety of emerging platelet storage technologies with respect to preserving platelet hemostatic function and preventing an adverse inflammation response.			
Title: Combat Trauma Therapies	5.026	4.345	3.508
Description: This effort focuses on work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from battlefield injuries. ***FY 2014 Accomplishments:***			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 840 / *Combat Injury Mgmt*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Transitioned biofilm (an aggregate of microorganisms in which cells adhere to each other on a surface) diagnostics, drugs that disrupt biofilm formation, and biofilm treatment therapies to clinical evaluation. Evaluated an FDA-approved, point-of-care, stem cell implant device in a clinical trial to determine whether it improves muscle function following large-volume muscle loss. ***FY 2015 Plans:*** Perform analysis supporting development of a predictive model to estimate dental casualties for Soldiers entering a theater of operations. Continue research to improve repair of large volume muscle loss injuries using stem cell technologies, biological scaffolds (tissue engineered graft), and autologous (individual as both donor and recipient) muscle tissue therapies (use muscle from uninjured area of body to replace lost muscle). ***FY 2016 Plans:*** As follow on to research from FY15, will evaluate therapies to reduce fibrosis (development of excessive connective tissue after injury) during recovery from large volume muscle loss injury and improve muscle functionality. Will perform small clinical studies to characterize effects of traumatic and burn injuries on vital organ preservation, scarring, and need for pain-relieving drugs. Will field an information product on a predictive model to estimate dental casualties for Soldiers entering a theater of operations.			
Title: Traumatic Brain Injury ***Description:*** This effort supports work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from concussive penetrating brain injuries. In FY2013 and FY2014, this effort supports Technology-Enabled Capability Demonstration 7.d, Brain in Combat. ***FY 2014 Accomplishments:*** Continued clinical pivotal study to validate an assay to diagnose presence and severity of TBI at or near point of injury; continued clinical trial of candidate drug for treatment of TBI; and continued work to identify combination therapeutics that mitigate or reduce effects of TBI for Advanced Development and clinical trials. ***FY 2015 Plans:*** Continue pivotal clinical study to validate an assay to diagnose presence and severity of TBI at or near point of injury; will continue clinical trial of candidate drug for treatment of TBI; and will continue work to identify combination therapeutics that mitigate or reduce effects of TBI for advanced development and clinical trials ***FY 2016 Plans:*** Will examine promising therapies to protect brain cells following TBI using relevant animal models of penetrating and concussive TBI. Will perform studies to establish drug protocols targeting the sub-acute (within the first few days following TBI) and chronic	3.302	3.658	4.062

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 840 / *Combat Injury Mgmt*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
TBI recovery phases. Will continue research from FY15 to evaluate effectiveness (therapeutic effect or benefit) of different drug combinations to protect brain cells following TBI and prevent seizures.			
Title: Combat Critical Care Engineering ***Description:*** This effort supports development of diagnostic and therapeutic medical devices, algorithms, software, and data-processing systems for resuscitation (to revive), stabilization and life support, and development of improved critical care nursing practices to improve care of severely injured or ill casualties during transport and in theater hospitals and development and evaluation of technologies to treat vital organ failure caused by traumatic injury. ***FY 2014 Accomplishments:*** Conducted in-human validation studies of advanced algorithms that measure tissue blood flow, metabolism, and oxygenation and evaluated ventilation strategies to improve neurologic (brain) status in casualties with TBI. ***FY 2015 Plans:*** Translate new arterial waveform (a graph obtained by monitoring the pressure in the arteries produced by the pumping of the heart) features to the development of algorithms for early identification of patients at greatest risk for developing shock. Continue research on ventilation strategies to improve brain status in casualties with TBI. Perform studies to identify means to improve critical care nursing practice in theater hospitals. ***FY 2016 Plans:*** Will evaluate militarily relevant pre-hospital care technologies used in existing civilian trauma system, including improved patient monitors with decision support algorithms to predict shock, life-saving intervention technologies and evaluation of telehealth direction of remote surgical procedure. Will conclude work on ventilation strategies and transition to advanced development. Will start clinical studies to support development of combat nursing clinical practice guidelines for en route care and for management of sepsis (potentially life-threatening complication of infection) in the burn intensive care unit. Will perform translational studies of promising technologies to treat single and multiple organ failure due to trauma.	4.227	2.948	3.692
Title: Clinical and Rehabilitative Medicine ***Description:*** This effort supports clinical studies of treatment of ocular and visual system traumatic injury, as well as restoration of function and appearance by regenerating skin, muscle, bone tissue, and soft tissue (including the genitalia and abdomen), in battle-injured casualties. Areas of interest for regenerative medicine include healing without scarring, repair of compartment syndrome (muscle and nerve damage following reduced blood flow caused by swelling), replacement skin, and facial reconstruction. ***FY 2014 Accomplishments:***	9.063	10.857	11.554

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 840 / *Combat Injury Mgmt*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Evaluated the preclinical safety and effectiveness of promising drug delivery, diagnostic, tissue repair, and/or treatment strategies for traumatic eye injury; continued to conduct clinical research for rehabilitation strategies for traumatic eye injury. Incrementally built upon past successes to develop novel drug delivery, diagnostic, reconstructive, and regenerative strategies; utilized and refined cell-based therapies (including stem cells[primitive cells that give rise to more specialized cell types as they develop]) and tissue scaffolds (tissue engineered grafts) to assess soft and hard tissue repair; regeneration safety and effectiveness; and also built upon promising approaches from FY2013 by continuing the clinical evaluation of candidate strategies for burn, scar-less wound healing, bone and soft tissue repair, and strategies to repair extremities, craniomaxillofacial (head, neck, face and jaw), genitalia, and abdominal regions. ***FY 2015 Plans:*** Conduct preclinical studies on drug delivery, diagnostic, tissue repair, and/or treatment strategies for traumatic eye injury and evaluate the preclinical safety and efficacy of promising strategies to facilitate clinical transition. Further develop novel drug delivery, diagnostic, reconstructive, and regenerative strategies including novel biological materials and cell-based therapies for clinical transition; utilize and refine cell-based therapies (including stem cells) and tissue scaffolds to restore soft and bone tissue form and function; perform preclinical safety and efficacy studies; build upon promising approaches from FY2014 by continuing the clinical evaluation of candidate strategies for burn, scarless wound healing, bone and soft tissue repair, and strategies to repair the tissues of the extremities, craniomaxillofacial, genital and abdominal body regions. ***FY 2016 Plans:*** Will execute preclinical studies of drug delivery, diagnostic, tissue repair, and/or treatment strategies for traumatic eye injury and assess the preclinical safety and efficacy of promising strategies to facilitate clinical translation. Will further advance novel drug delivery, diagnostic, reconstructive, and regenerative strategies including novel biological materials and cell-based therapies for clinical translation; utilize and refine cell-based therapies (including stem cells) and tissue scaffolds to restore soft and bone tissue form and function; will establish preclinical safety and efficacy studies; will enhance promising approaches from FY2015 by advancing the clinical evaluation of candidate strategies for burn, scarless wound healing, bone and soft tissue repair, and strategies to repair the tissues of the extremities, craniomaxillofacial, genitalia and abdominal body regions. Improved monitoring technologies for tissue rejection during hand and face transplant procedures and craniofacial bone grafts to advance into clinical trials.			
Title: Administrative Activities for Prior Year Clinical Trials ***Description:*** Contract law requires the government to fulfill its responsibilities for the life of the Congressional Special Interest (CSI) award as stated in the terms and conditions. Each award may have an execution and award management tail of up to 5 years post-award, which usually occurs 18 months after the start of the fiscal year. ***FY 2014 Accomplishments:***	2.099	0.560	0.556

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 840 / *Combat Injury Mgmt*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Continued funding for scientific expertise, legal, contracting, research protections, regulatory affairs, and resource support personnel to manage active projects in FY2014 to be closed out over the POM. ***FY 2015 Plans:*** Continue funding for scientific expertise, legal, contracting, research protections, regulatory affairs, and resource support personnel to manage active projects in FY2015 to be closed out over the POM ***FY 2016 Plans:*** Will continue funding for scientific expertise, legal, contracting, research protections, regulatory affairs, and resource support personnel to manage active projects in FY2016 to be closed out over the POM.			
Accomplishments/Planned Programs Subtotals	30.633	29.321	30.572

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army											Date: February 2015	
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*				Project (Number/Name) 945 / *BREAST CANCER STAMP PROCEEDS*			
COST ($ in Millions)	**Prior Years**	**FY 2014**	**FY 2015**	**FY 2016 Base**	**FY 2016 OCO**	**FY 2016 Total**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**Cost To Complete**	**Total Cost**
945: *BREAST CANCER STAMP PROCEEDS*	-	0.497	-	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

This project receives funds as proceeds from the sale of Breast Cancer Stamps.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
Congressional Add: Breast Cancer Stamp Proceeds	0.497	-
FY 2014 Accomplishments: Breast Cancer Stamp Proceeds		
Congressional Adds Subtotals	0.497	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army			Date: February 2015
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) 97T / *NEUROTOXIN EXPOSURE TREATMENT*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
97T: *NEUROTOXIN EXPOSURE TREATMENT*	-	16.000	16.000	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Neurotoxin Exposure Treatment.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
Congressional Add: Peer-Reviewed Neurotoxin Exposure Treatment Parkinsons Research Program	16.000	16.000
FY 2014 Accomplishments: Neurotoxin Exposure Treatment Parkinsons Research Program		
FY 2015 Plans: Neurotoxin Exposure Treatment Parkinsons Research Program		
Congressional Adds Subtotals	16.000	16.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army			Date: February 2015
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) FH4 / *Force Health Protection - Adv Tech Dev*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
FH4: *Force Health Protection - Adv Tech Dev*	-	1.606	1.691	1.268	-	1.268	1.332	1.776	1.868	1.905	-	-

A. Mission Description and Budget Item Justification

This project maturates, demonstrates, and supports enhanced Force Health Protection of Soldiers against threats in military operations and training. Health-monitoring tools are matured to rapidly identify deployment stressors that affect the health of Joint Forces. The key databases supporting this program are the Millennium Cohort Study and the Total Army Injury and Health Outcomes Database. These databases and systems enhance the DoD's ability to monitor and protect against adverse changes in health, especially psychological/ mental health effects caused by changes in brain function. Force Health Protection work is conducted in close coordination with the Department of Veterans Affairs. The program is maturing the development of holistic health monitoring (e.g., development of neuropsychological evaluation methods) and validating subclinical signs and symptoms correlating to medical records, diagnosed diseases, and mortality rates across a Soldier's career. These databases allow for the examination of interactions of psychological (mental) stress and other deployment and occupational stressors that affect Warfighter health behaviors.

This project contains no duplication with any effort within the Military Departments and includes direct participation by other Services. The cited work is fully coordinated with Natick Soldier Research Development Engineering Command (NSRDEC), Natick, MA.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this project is performed by the U.S. Army Center for Environmental Health Research (USACEHR), Fort Detrick, MD; USARIEM, Natick, MA; and the Naval Health Research Center (NHRC), San Diego, CA.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Health Research	1.606	1.691	1.268
Description: This effort develops and validates novel tools and strategies to advance individualized operational exposure dosimetry (measures of exposure) and establish dose-response links between operational exposures and neurological (of or about the nerves and nervous system) and physical health. Dosimetry tools may include new technologies, human biomarkers (biologically derived indicator of a process, event or condition, e.g. protein), objective physiologic markers, physiological) modeling, and validated algorithms to evaluate the health effects of military service, including deployments, and methods to detect a Soldier's exposure to environmental contamination and/or toxic substances, e.g. toxic industrial chemicals (TIC).			
FY 2014 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** FH4 / *Force Health Protection - Adv Tech Dev*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Assessed modifiable behaviors and emerging health concerns among Service members using survey data and other health outcome measures and assessed validity of health screening instruments/surveys and other health measures. This data led to a greater understanding of the impact of physical and mental health issues for Service members. This effort provided screening and preventive strategies to decrease negative health consequences and inform DoD polices. ***FY 2015 Plans:*** Assess modifiable behaviors and those resilience factors that protect Service Members from adverse mental or physical health outcomes. Assess the economic burden of negative coping behaviors such as alcohol and tobacco use. This effort provides screening factors to assess military Family well-being and resilience. ***FY 2016 Plans:*** Will advance and deliver innovative tools, approaches, and models for detecting and measuring a Soldier' exposure to potentially toxic substances during operations. . Will provide dose-response links between operational exposures and neurological and physical health / well-being. Will provide models for predicting the likelihood of neurological or physical injury as a result of operational exposure(s) to TICs. Will deliver evidence-based guidance to inform policy makers to refine guidelines for individualized operational exposure dosimetry linked to neurological and physical injury.			
Accomplishments/Planned Programs Subtotals	1.606	1.691	1.268

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army												Date: February 2015
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*				Project (Number/Name) MM2 / *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*			
COST ($ in Millions)	**Prior Years**	**FY 2014**	**FY 2015**	**FY 2016 Base**	**FY 2016 OCO**	**FY 2016 Total**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**Cost To Complete**	**Total Cost**
MM2: *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*	-	8.000	8.000	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Medical Advanced Technology Initiatives.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
Congressional Add: Military Burn Trauma Research Program	8.000	8.000
FY 2014 Accomplishments: Military Burn Trauma Research Program		
FY 2015 Plans: Military Burn Trauma Research Program		
Congressional Adds Subtotals	8.000	8.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army			Date: February 2015
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) MM3 / *Warfighter Medical Protection & Performance*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
MM3: *Warfighter Medical Protection & Performance*	-	11.814	17.983	19.025	-	19.025	19.148	18.935	19.201	19.582	-	-

A. Mission Description and Budget Item Justification

This project supports the Medical and Survivability technology areas of the future force with laboratory validation studies and field demonstrations of biomedical products designed to protect, sustain, and enhance Soldier performance in the face of myriad environmental and physiological (human physical and biochemical functions) stressors and materiel hazards encountered in training and operational environments. This effort focuses on demonstrating and transitioning technologies as well as validated tools associated with biomechanical-based health risks, injury assessment and prediction, Soldier survivability, and performance during continuous operations. The four main thrust areas are (1) Physiological Health, (2) Environmental protection, (3) Injury Prevention and Reduction and (4) Psychological (mental) Health and Resilience.

This project contains no duplication with any effort within the Military Departments and includes direct participation by other Services. The cited work is fully coordinated with Natick Soldier Research Development (NSRDEC), Natick, MA.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this project is performed by the United States Army Research Institute of Environmental Medicine (USARIEM), Natick, MA, and United States Army Aeromedical Research Laboratory (USAARL), Fort Rucker, AL.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Physiological (human physical and biochemical functions) Health and Environmental Protection (Sleep Research/ Environmental Monitoring)	1.629	1.698	2.736
Description: This effort supports and matures laboratory prototypes, nutritional interventions, and decision aids for the validation of physiological status and prediction of Soldier performance in extreme environments. This effort supports Technology-Enabled Capability Demonstration 1.b, Force Protection--Soldier and Small Unit in FY2014-2016 and also supports capability demonstrations in the area of decreasing Soldier physical burden in FY2014-2016.			
FY 2014 Accomplishments: Demonstrated the effectiveness of nutritional interventions for facilitating wound healing and supporting immune function; demonstrated real-time physiological status monitoring systems for operational use in-theater; enhanced injury prediction			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** MM3 / *Warfighter Medical Protection & Performance*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
algorithms for incorporation into wearable sensor systems; and enabled the prediction and prevention of physical injury and health outcomes. ***FY 2015 Plans:*** Perform field-studies to demonstrate the efficacy of nutritional interventions for optimizing Warrior recovery from physical and mental injury. Validate algorithms and mathematical models capable of predicting cognitive status and monitoring recovery and healing from physical injury. ***FY 2016 Plans:*** Will verify that nutritional approaches enhance recovery of brain function after injury. Will demonstrate dining hall interventions that improve Warfighter diet quality. Will validate models that can accurately predict recovery and safe return-to-duty.			
Title: Environmental Health and Protection - Physiological (human physical and biochemical functions) Awareness Tools and Warrior Sustainment in Extreme Environments. ***Description:*** This effort supports and maturates non-invasive technologies, decision-aid tools, and models to enhance Warrior protection and sustainment across the operational spectrum. This effort supports Technology-Enabled Capability Demonstration 1.b, Force Protection--Soldier and Small Unit in FY2013-2014, and also supports capability demonstrations in the area of decreasing Soldier physical burden. ***FY 2014 Accomplishments:*** Determined the prototype noninvasive hydration sensor technologies that meet requirements for clinical precision and reliability. This technology was used to determine Warrior hydration status and inform appropriate clinical intervention and reduce the incidence of heat injuries among Warriors. ***FY 2015 Plans:*** Conduct a feasibility study to determine saliva biomarker panel to distinguish levels of dehydration in exertional exercise to prevent heat injury. Validate organ damage biomarkers correlation to clinical measures in heat stroke patients. Determine efficacy of drug treatments for heat injury and heat stroke recovery. Provide strategies for localized heating to optimize hand and finger dexterity for specific military tasks. Exploit nanomaterials (materials smaller than a one tenth of a micrometer in at least one dimension) for developing advanced focused heating approaches to prevent nonfreezing cold injury. Evaluate the efficacy of new pharmaceuticals to prevent acute mountain sickness and improve work performance at high altitude. ***FY 2016 Plans:*** Will validate biomarkers of heat injured organ damage to clinical outcome measures. Will validate effectiveness of interventions including targeted drug treatments for recovery from heat injury. Will transition altitude sickness, acclimatization and task performance models to physiological status monitoring system(s) for end-user field validation studies. Will refine localized heating	1.080	2.356	1.759

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** MM3 / *Warfighter Medical Protection & Performance*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
strategies to improve hand dexterity and develop a militarily-relevant dexterity assessment method for cold weather operations and provide policy guidance for validated intervention strategies.			
Title: Injury Prevention and Reduction (Physical Performance Enhancement) ***Description:*** This effort supports and validates injury prediction tools for brain, spine, and chest injury from blast, blunt, and ballistic impact. This effort supports Technology-Enabled Capability Demonstration 1.b, Force Protection--Soldier and Small Unit in FY2014-2016, and also supports capability demonstrations in the area of decreasing Soldier physical burden in FY2014-2016. ***FY 2014 Accomplishments:*** Upgraded the blast, blunt trauma, and inhalation performance decrement software to incorporate extreme environmental stressors; matured musculoskeletal models for predicting physical performance injury and health outcomes for military-relevant tasks, accounting for individual variations, equipment, and environmental factors. ***FY 2015 Plans:*** Provide medical standards for protection against hearing and vestibular injuries and ensure compatibility with military operations and maintenance of Warfighter situational awareness. Develop and validate improved sensory system injury countermeasures. Develop and validate computational models to predict the effects of the primary blast wave on the face and eyes. Develop field-forward, non-invasive tools that will aid medical staff decisions regarding treatment, prognosis, and return-to-duty following muscle and/or other tissue injury. ***FY 2016 Plans:*** Will work with combat developers to provide active and passive hearing protection standards. Will refine and validate model(s) for predicting effects of hearing loss on speech intelligibility with hearing protection (FY15 6.2 work). Will refine standards for improved sensory system countermeasures to be used by aircrew in degraded visual environments. Will validate computational models that predict the effects of the primary blast wave on the face and eyes and incorporate into a decision aid for transition to commanders.	5.397	3.760	4.101
Title: Psychological Health and Resilience ***Description:*** This effort supports and validates neurocognitive (relating to or involving the central nervous system and cognitive abilities) assessment and brain injury detection methods; and validates tools and preclinical methods to treat post-traumatic stress disorder in a military population. This effort also supports validation of interventions in Warfighters for post-traumatic stress disorder (PTSD), validation of biomarkers of PTSD symptomatology, validation of methods to follow effectiveness of PTSD treatments, validation of neuroprotective (protection of nerves and nervous system) interventions and validation of strategies to prevent neurocognitive deficits (reduced ability to learn and comprehend) and symptomatology associated with brain injury. This effort supports Technology Enabled Capability Demonstration 7.d, Brain In Combat, in FY2014-2016.	3.708	10.169	10.429

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** MM3 / *Warfighter Medical Protection & Performance*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
FY 2014 Accomplishments: Demonstrated the utility of magnetoencephalography (technique for mapping brain activity by recording magnetic fields produced by electrical currents occurring naturally in the brain), to differentiate between PTSD and mild TBI; the utility of circulating blood biomarkers for effective assessment of acute brain injury post-concussion symptoms; and demonstrated whether neurocognitive testing can accurately inform assessment of the brain injury following a post-concussion event. These efforts led to more effective assessments of Warriors and facilitated improved strategies for appropriate care and identified better treatment modalities for brain injury following a concussion event. ***FY 2015 Plans:*** Provide guidance on the use of sleep measures to aid in the diagnosis, prognosis, and monitoring of recovery from a concussive event. Determine the utility of neurocognitive assessment tools in conjunction with physiological (human physical and biochemical functions) data from other sources, such as blood biomarkers, for assessment of post-concussive symptoms. Validate algorithms that predict concussion injury and incorporate these into currently available blast-wave concussion sensor systems. Evaluate the efficacy of bright light therapy for PTSD treatment. Determine the gender-relevant signatures of PTSD and the changes in biomarker levels associated with PTSD onset during deployment. ***FY 2016 Plans:*** Will continue to validate previously developed strategies to reduce vulnerability to concussive injury during blast and impact exposures and promote recovery from concussion. Will initiate investigation into the correlation of detailed PTSD symptomatology/ behavioral data with genomic, proteomic, and metabolic biomarkers for stratification of PTSD into subtypes. Will collect specimens pre- and post-treatment for identification of blood biomarkers associated with treatment response and identification of predictive markers associated with successful exposure therapy treatment. Will continue collaborative support for research and data analysis with the Army University Affiliated Research centers, the University of California Santa Barbara Institute for Collaborative Biotechnologies and SBE.			
Accomplishments/Planned Programs Subtotals	11.814	17.983	19.025

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** MM3 / *Warfighter Medical Protection & Performance*

E. Performance Metrics

N/A