

**UNCLASSIFIED**

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Army										Date: March 2014		
Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army / BA 3: Advanced Technology Development (ATD)					R-1 Program Element (Number/Name) PE 0603002A / MEDICAL ADVANCED TECHNOLOGY							
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
Total Program Element	-	99.924	100.999	67.291	-	67.291	70.050	68.800	71.291	72.388	-	-
810: Ind Base Id Vacc&Drug	-	18.782	17.404	18.274	-	18.274	18.837	16.789	17.986	18.160	-	-
814: NEUROFIBROMATOSIS	-	13.915	15.000	-	-	-	-	-	-	-	-	-
840: Combat Injury Mgmt	-	32.615	31.527	29.334	-	29.334	30.783	31.398	32.460	33.020	-	-
945: BREAST CANCER STAMP PROCEEDS	-	0.602	-	-	-	-	-	-	-	-	-	-
97T: NEUROTOXIN EXPOSURE TREATMENT	-	15.979	16.000	-	-	-	-	-	-	-	-	-
FH4: Force Health Protection - Adv Tech Dev	-	1.488	1.661	1.692	-	1.692	1.276	1.340	1.788	1.880	-	-
MM2: MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)	-	7.076	8.000	-	-	-	-	-	-	-	-	-
MM3: Warfighter Medical Protection & Performance	-	9.467	11.407	17.991	-	17.991	19.154	19.273	19.057	19.328	-	-
# The FY 2015 OCO Request will be submitted at a later date.												
<b>Note</b> FY13 adjustments attributed to Sequestration reductions (-7.603 million) and Congressional Add (39 million). FY14 adjustments attributed to FFRDC reduction (-33 thousand) and Congressional Add (39 million).												
<b>A. Mission Description and Budget Item Justification</b> This program element (PE) matures 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. Tri-Service coordination 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 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												

# UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Army		Date: March 2014
Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army / BA 3: Advanced Technology Development (ATD)	R-1 Program Element (Number/Name) PE 0603002A / MEDICAL ADVANCED TECHNOLOGY	
<p>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.</p> <p>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) Committee. The ASBREM Committee serves to facilitate coordination and prevent unnecessary duplication of effort within the Department of Defenses biomedical research and development community, as well as its associated enabling research areas.</p> <p>Project 810 matures 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.</p> <p>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.</p> <p>Project FH4 matures, 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.</p>		

# UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Army		Date: March 2014			
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			
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 (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 Houston, TX; and U.S. Army Center for Environ. Health Research and the Armed Forces Institute of Regenerative Medicine.					
B. Program Change Summary (\$ in Millions)	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO	FY 2015 Total
Previous President's Budget	69.580	62.032	65.167	-	65.167
Current President's Budget	99.924	100.999	67.291	-	67.291
Total Adjustments	30.344	38.967	2.124	-	2.124
• Congressional General Reductions	-0.171	-0.033			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	39.000	39.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	0.602	-			
• SBIR/STTR Transfer	-1.484	-			
• Adjustments to Budget Years	-	-	2.124	-	2.124
• Other Adjustments	-7.603	-	-	-	-

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Army										Date: March 2014		
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 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
810: Ind Base Id Vacc&Drug	-	18.782	17.404	18.274	-	18.274	18.837	16.789	17.986	18.160	-	-

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

## **A. Mission Description and Budget Item Justification**

This project matures 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 U.S. military deployed 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 biting insects and other vectors 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.

**UNCLASSIFIED**

Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014		
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 2013	FY 2014	FY 2015
<b>Title:</b> Drugs to Prevent/Treat Parasitic Diseases  <b>Description:</b> This effort selects promising malaria and leishmaniasis (a disease transmitted by sand flies) drug candidates for testing in humans, prepares data packages required for FDA approval of testing in humans, and conducts 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.  <b>FY 2013 Accomplishments:</b> Evaluated effectiveness of new anti-parasitic drugs through testing in human populations exposed to malaria and leishmania infections. These drugs previously showed promising results in animal testing.  <b>FY 2014 Plans:</b> Assess effectiveness of new and refined anti-parasitic drugs through testing in human populations exposed to malaria and leishmania infections world-wide.  <b>FY 2015 Plans:</b> Will advance new generation drugs with improved therapeutic index through small animal model testing. Will perform clinical testing for safety and effectiveness of new selected candidate drugs and drug combinations. Will transition best therapeutic and preventive drug candidates to advanced development.		2.381	2.247	2.220
<b>Title:</b> Vaccines for Prevention of Malaria  <b>Description:</b> 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.  <b>FY 2013 Accomplishments:</b>		5.717	5.401	5.125

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014		
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 2013	FY 2014	FY 2015
Conducted clinical trials of multiple types of vaccines in human populations using laboratory-based human challenge model. Then, for promising candidates, optimized administration for testing in human populations naturally exposed to malaria. Transitioned successful vaccine candidate to Advanced Development for further testing. <b>FY 2014 Plans:</b> Conduct clinical trials of new formulations of vaccine candidates to assess safety and effectiveness in humans and assess vaccine performance for suitability for transition to Advanced Development. <b>FY 2015 Plans:</b> Will continue to conduct clinical trials of new formulations of vaccine candidates in human volunteers to assess their safety and effectiveness for transition into Advanced Development. Will down select lead P. falciparum (severe form of malaria) vaccine candidates for transition into Advanced Development.				
<b>Title:</b> Bacterial Disease Threats <b>Description:</b> 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. <b>FY 2013 Accomplishments:</b> Conducted second human clinical trial for E. coli vaccines to determine the best candidate vaccine, route of administration, and dosage; conducted additional human clinical trials on best Shigella vaccine based on FY2012 human trial results; and evaluated results of Campylobacter clinical trial conducted in FY2012. <b>FY 2014 Plans:</b> Produce best vaccine candidates by using Good Manufacturing Practices developed by the FDA; conduct safety trials of additional promising vaccine candidates against three diarrheal pathogens (infectious agents) of interest (Shigella, Campylobacter, and E. coli) in human volunteers. <b>FY 2015 Plans:</b> Will conduct expanded safety and effectiveness clinical trials in human volunteers with two diarrheal pathogens (infectious agents), Shigella, and enterotoxigenic E. coli, vaccine candidates for assessment of their extended safety and effectiveness. Will transition best down-selected vaccine candidates to Advanced Development only if successful.		5.508	5.272	4.917
<b>Title:</b> Viral Disease Threats <b>Description:</b> This effort selects the most promising vaccine candidates for evaluation in human subjects against human immunodeficiency virus (HIV), 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). Conduct FDA-		3.263	2.752	4.887

**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army		<b>Date:</b> March 2014	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / MEDICAL ADVANCED TECHNOLOGY	<b>Project (Number/Name)</b> 810 / Ind Base Id Vacc&Drug	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>
required nonclinical safety and protection testing (laboratory-based) in animals, prepare FDA investigational new drug technical data packages, and conduct clinical testing of candidate vaccines in humans.			
<p><b>FY 2013 Accomplishments:</b> Demonstrated the concept of a prime-boost dengue virus vaccine strategy, which stimulates different parts of the immune system and enhances the body's overall immune response, to improve current vaccine and reduce developmental risk; conducted further clinical testing of dengue vaccine candidates; further developed the hantavirus vaccine with support of a commercial partner to include evaluation of vaccine delivery methods to improve effectiveness and safety; transition to Advanced Development; and prepared and conducted safety studies in human volunteers with new HIV vaccine candidates at multiple sites worldwide.</p> <p><b>FY 2014 Plans:</b> Evaluate the alternative strategies to deliver vaccine candidates in human muscle and skin to develop a needle-free injection; explore 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 evaluate human safety and effectiveness of best vaccine candidates against all dengue types present worldwide.</p> <p><b>FY 2015 Plans:</b> Will 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. Will initiate expanded clinical testing for efficacy studies with multivalent dengue vaccine in US adults with new vaccine lots. Will also initiate clinical studies for efficacy in dengue endemic countries with best down-selected candidates. Will refine the final vaccine formulation and delivery into human body. Will 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.</p>			
<p><b>Title:</b> Diagnostics and Disease Transmission Control</p> <p><b>Description:</b> This effort conducts human subject testing of FDA-regulated field medical diagnostic devices and EPA-approved measures to control insect-borne pathogens (infectious agents) and diseases such as Q fever (sand fly fever), Japanese encephalitis, Rickettsial disease (carried by ticks, fleas, and lice), and other pathogens transmitted by insects.</p> <p><b>FY 2013 Accomplishments:</b> Completed field evaluation of passive arthropod (animals without a backbone with segmented bodies and jointed limbs, such as a scorpion, crab, or centipede)-repellent systems that do not require application of chemicals to skin or clothing; completed field evaluations on prototype rapid diagnostic kits developed for the detection of selected vector-borne pathogens (pathogens transmitted by insects, such as malaria, leishmania, and dengue virus); completed the development of an enteric assay to</p>		1.913	1.732
			1.125

# UNCLASSIFIED

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army		<b>Date:</b> March 2014	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / MEDICAL ADVANCED TECHNOLOGY	<b>Project (Number/Name)</b> 810 / Ind Base Id Vacc&Drug	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>
<p>transition the assay to Advanced Development; and completed field evaluations and FDA-required 510K clearance on the Dengue Rapid Diagnostic Device.</p> <p><b>FY 2014 Plans:</b> Initiate 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, such as a mosquito) transmitting medically relevant diseases; conduct field evaluation of the new alternate repellent products in overseas field locations; and evaluate the NGDS assays (tests) for use in diagnosing pathogens (infectious agents) in humans.</p> <p><b>FY 2015 Plans:</b> Will develop Rapid Human Diagnostic Devices in collaboration with industry partners and transition to Advanced Development. Will test vector (organisms that transmit disease) surveillance devices in field. Will test new vector control technologies with field applications and select best tools for military operations.</p>			
<b>Accomplishments/Planned Programs Subtotals</b>		18.782	17.404
<b>C. Other Program Funding Summary (\$ in Millions)</b>			
N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b>			
N/A			
<b>E. Performance Metrics</b>			
N/A			



**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army										<b>Date:</b> March 2014																										
<b>Appropriation/Budget Activity</b> 2040 / 3					<b>R-1 Program Element (Number/Name)</b> PE 0603002A / MEDICAL ADVANCED TECHNOLOGY				<b>Project (Number/Name)</b> 814 / NEUROFIBROMATOSIS																											
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015 Base</b>	<b>FY 2015 OCO #</b>	<b>FY 2015 Total</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>Cost To Complete</b>	<b>Total Cost</b>																								
814: NEUROFIBROMATOSIS	-	13.915	15.000	-	-	-	-	-	-	-	-	-																								
<p># The FY 2015 OCO Request will be submitted at a later date.</p> <p><b>A. Mission Description and Budget Item Justification</b> Congressional Interest Item funding for Neurofibromatosis research.</p> <p><b>B. Accomplishments/Planned Programs (\$ in Millions)</b></p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th><b>FY 2013</b></th> <th><b>FY 2014</b></th> <th><b>FY 2015</b></th> </tr> </thead> <tbody> <tr> <td><b>Title:</b> Neurofibromatosis Research Program</td> <td align="right">13.915</td> <td align="right">15.000</td> <td align="center">-</td> </tr> <tr> <td colspan="4"><b>Description:</b> This congressionally directed project conducted research on Neurofibromatosis.</td> </tr> <tr> <td colspan="4"><b>FY 2013 Accomplishments:</b> Neurofibromatosis Research Program</td> </tr> <tr> <td colspan="4"><b>FY 2014 Plans:</b> Neurofibromatosis Research Program</td> </tr> <tr> <td align="right" colspan="2"><b>Accomplishments/Planned Programs Subtotals</b></td> <td align="right">13.915</td> <td align="right">15.000</td> </tr> </tbody> </table> <p><b>C. Other Program Funding Summary (\$ in Millions)</b> N/A</p> <p><b>Remarks</b></p> <p><b>D. Acquisition Strategy</b> N/A</p> <p><b>E. Performance Metrics</b> N/A</p>														<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>Title:</b> Neurofibromatosis Research Program	13.915	15.000	-	<b>Description:</b> This congressionally directed project conducted research on Neurofibromatosis.				<b>FY 2013 Accomplishments:</b> Neurofibromatosis Research Program				<b>FY 2014 Plans:</b> Neurofibromatosis Research Program				<b>Accomplishments/Planned Programs Subtotals</b>		13.915	15.000
	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>																																	
<b>Title:</b> Neurofibromatosis Research Program	13.915	15.000	-																																	
<b>Description:</b> This congressionally directed project conducted research on Neurofibromatosis.																																				
<b>FY 2013 Accomplishments:</b> Neurofibromatosis Research Program																																				
<b>FY 2014 Plans:</b> Neurofibromatosis Research Program																																				
<b>Accomplishments/Planned Programs Subtotals</b>		13.915	15.000																																	

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Army										Date: March 2014		
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 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
840: Combat Injury Mgmt	-	32.615	31.527	29.334	-	29.334	30.783	31.398	32.460	33.020	-	-

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

## 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, and prognostics and diagnostics for life support systems. Post-evacuation medical research focuses on continued care and rehabilitative medicine for extremity (arms and legs), 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), 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.

**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army		<b>Date:</b> March 2014	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / MEDICAL ADVANCED TECHNOLOGY	<b>Project (Number/Name)</b> 840 / Combat Injury Mgmt	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>
<b>Title:</b> Damage Control Resuscitation  <b>Description:</b> This effort supports work required to validate safety and effectiveness of drugs and medical procedures to maintain metabolism and minimize harmful inflammation after major trauma. Efforts focus on blocking complement activation (a series of disease-fighting proteins and their reactions in the body) from damaging healthy cells of the body and preventing or minimizing secondary organ failure (including brain and spinal cord injury).  <b>FY 2013 Accomplishments:</b> Continued coagulation (blood clotting) factor and platelet function studies of ways to stop bleeding and studied the use of compounds to reduce inflammation as a therapy for bleeding caused by trauma.  <b>FY 2014 Plans:</b> Evaluate devices, biologics (medical products derived from living organisms), and techniques to control life-threatening internal bleeding caused by injuries to the chest and abdomen; continue studies of drugs and biologics to reduce inflammation as therapy for traumatic bleeding and develop laboratory assays and clinical practice guidelines for diagnosis of impaired blood clotting ability caused by trauma; and validate an improved blood platelet storage technology for far-forward use.  <b>FY 2015 Plans:</b> Will continue to evaluate medical products and techniques to control life threatening bleeding from areas of the body where tourniquets may not be effectively used, such as within the chest and abdomen, and from large soft tissue injuries and injuries to the armpit or groin. Will continue to evaluate drugs and biologics (medical products derived from living organisms) to reduce traumatic bleeding caused by inflammation. Will conduct preliminary studies to help determine optimal conditions for extension of platelet (a cell in blood that helps it clot) storage duration and maintenance of blood-clotting capability concurrently to support continued validation studies of novel blood platelet storage technologies for far-forward use.		7.055	7.118
<b>Title:</b> Combat Trauma Therapies  <b>Description:</b> This effort focuses on work required to validate safety and effectiveness of drugs, biologics (products derived from living organisms), and medical procedures intended to minimize immediate and long-term effects from battlefield injuries.  <b>FY 2013 Accomplishments:</b> Conducted small-scale clinical trials for most promising therapies for loss of large volumes of muscle and wound healing agents.  <b>FY 2014 Plans:</b>		5.449	5.173
			4.347

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014		
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)				
Transition biofilm diagnostics, drugs that disrupt biofilm (an aggregate of microorganisms in which cells adhere to each other on a surface) formation, and therapies to clinical evaluation and evaluate a 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 2013	FY 2014	FY 2015
<b>FY 2015 Plans:</b> Will perform analysis to support development of a predictive model to estimate dental casualties for Soldiers entering a theater of operations. Will continue research to improve repair of large volume muscle loss injuries using stem cell technologies, biological scaffolds (tissue engineered graft), and autologous muscle tissue therapies (use muscle from uninjured area of body to replace lost muscle).				
<b>Title:</b> Traumatic Brain Injury <b>Description:</b> This effort supports work required to validate safety and effectiveness of drugs, biologics (products derived from living organisms), and medical procedures intended to minimize immediate and long-term effects from penetrating brain injuries. In FY2013 and FY2014, this effort supports Technology-Enabled Capability Demonstration 7.d, Brain in Combat. <b>FY 2013 Accomplishments:</b> Identified combination therapeutics for Advanced Development/clinical trials for TBI that substantially mitigated or reduced TBI-induced non-convulsive seizures and brain damage. <b>FY 2014 Plans:</b> Continue/finish clinical pivotal study to validate assay (test) to diagnose presence and severity of TBI at or near point of injury; continue clinical trial of candidate drug for treatment of TBI; and continue work to identify combination therapeutics that mitigate or reduce effects of TBI for Advanced Development and clinical trials. <b>FY 2015 Plans:</b> Will continue clinical pivotal study to validate assay (test) 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		3.046	3.398	3.660
<b>Title:</b> Combat Critical Care Engineering <b>Description:</b> This effort supports development of diagnostic and therapeutic medical devices, algorithms, software, and data-processing systems for resuscitation, stabilization, 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. <b>FY 2013 Accomplishments:</b>		3.376	4.350	2.949

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014		
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)				
Started clinical trials of machine-learning monitoring, using algorithms based on sensor data in multiple applications (early-onset of blood loss, blood loss volume, and risk for cardiovascular collapse) and transitioned vital signs technology to Advanced Development for further test and evaluation, FDA licensure, and for fielding.  <b>FY 2014 Plans:</b> Conduct in-human validation studies of advanced algorithms that measure tissue blood flow, metabolism, and oxygenation and evaluate ventilation strategies to improve neurologic (brain) status in casualties (those injured) with TBI.  <b>FY 2015 Plans:</b> Will 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 those patients at greatest risk for developing shock. Will continue research on ventilation strategies to improve brain status in casualties with traumatic brain injury. Will perform studies to identify means to improve critical care nursing practice in theater hospitals.				
<b>Title:</b> Clinical and Rehabilitative Medicine  <b>Description:</b> 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.  <b>FY 2013 Accomplishments:</b> Continued to develop drug delivery and diagnostic and tissue repair strategies, including stem cell therapies for traumatic eye injury; continued development and standardization of animal models to assess soft and hard tissue regeneration technologies; continued studies of burn, scarless wound, soft tissue, and bone repair strategies; continued development and testing of stem cell therapies and scaffolds (tissue-engineered grafts) in animal models; and continued the evaluation of candidate strategies for craniomaxillofacial (head, neck, face, and jaw) reconstruction, including wound-healing control and tissue engineering/regeneration techniques to restore facial features.  <b>FY 2014 Plans:</b> Evaluate the preclinical safety and effectiveness of promising drug delivery, diagnostic, tissue repair, and/or treatment strategies for traumatic eye injury; continue to conduct clinical research for rehabilitation strategies for traumatic eye injury; incrementally build upon past successes to develop novel drug delivery, diagnostic, reconstructive, and regenerative strategies; utilize and refine cell-based therapies (including stem cells) and tissue scaffolds (tissue-engineered grafts) to assess soft and hard tissue repair and regeneration safety and effectiveness; and also build upon promising approaches from FY2013 by continuing the		9.699	9.328	10.862

**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army		<b>Date:</b> March 2014	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / MEDICAL ADVANCED TECHNOLOGY	<b>Project (Number/Name)</b> 840 / Combat Injury Mgmt	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>
clinical evaluation of candidate strategies for burn, scarless wound healing, bone and soft tissue repair, and strategies to repair extremities (arms and legs), craniomaxillofacial (head, neck, face and jaw), genital, and abdominal regions.			
<b>FY 2015 Plans:</b> Will 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. Will 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 (tissue-engineered grafts) 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 (arms and legs), craniomaxillofacial (head, neck, face and jaw), genital, and abdominal body regions.			
<b>Title:</b> Administrative Activities for Prior Year Clinical Trials  <b>Description:</b> 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.		3.990	2.160
<b>FY 2013 Accomplishments:</b> Funded for scientific expertise, legal, contracting, research protections, regulatory affairs, and resource support personnel to manage 627 active projects in FY2012 to be closed out over the POM.			
<b>FY 2014 Plans:</b> Continue funding for scientific expertise, legal, contracting, research protections, regulatory affairs, and resource support personnel to manage active projects in FY2013 to be closed out over the POM.			
<b>FY 2015 Plans:</b> Will continue funding for scientific expertise, legal, contracting, research protections, regulatory affairs, and resource support personnel to manage active projects in FY2013 to be closed out over the POM			
<b>Accomplishments/Planned Programs Subtotals</b>		32.615	31.527
<b>C. Other Program Funding Summary (\$ in Millions)</b>			
N/A			
<b>Remarks</b>			

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / MEDICAL ADVANCED TECHNOLOGY	Project (Number/Name) 840 / Combat Injury Mgmt
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		

**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army										<b>Date:</b> March 2014																						
<b>Appropriation/Budget Activity</b> 2040 / 3					<b>R-1 Program Element (Number/Name)</b> PE 0603002A / MEDICAL ADVANCED TECHNOLOGY				<b>Project (Number/Name)</b> 945 / BREAST CANCER STAMP PROCEEDS																							
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015 Base</b>	<b>FY 2015 OCO #</b>	<b>FY 2015 Total</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>Cost To Complete</b>	<b>Total Cost</b>																				
945: BREAST CANCER STAMP PROCEEDS	-	0.602	-	-	-	-	-	-	-	-	-	-																				
<p># The FY 2015 OCO Request will be submitted at a later date.</p> <p><b>A. Mission Description and Budget Item Justification</b> This project receives funds as proceeds from the sale of Breast Cancer Stamps.</p> <p><b>B. Accomplishments/Planned Programs (\$ in Millions)</b></p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td></td> <td><b>FY 2013</b></td> <td><b>FY 2014</b></td> <td><b>FY 2015</b></td> </tr> <tr> <td><b>Title:</b> Breast Cancer Stamp Proceeds</td> <td align="center">0.602</td> <td align="center">-</td> <td align="center">-</td> </tr> <tr> <td><b>Description:</b> This is a Congressional Interest Item.</td> <td></td> <td></td> <td></td> </tr> <tr> <td><b>FY 2013 Accomplishments:</b> Breast Cancer Stamp Proceeds</td> <td></td> <td></td> <td></td> </tr> <tr> <td align="right"><b>Accomplishments/Planned Programs Subtotals</b></td> <td align="center">0.602</td> <td align="center">-</td> <td align="center">-</td> </tr> </table> <p><b>C. Other Program Funding Summary (\$ in Millions)</b> N/A</p> <p><b>Remarks</b></p> <p><b>D. Acquisition Strategy</b> N/A</p> <p><b>E. Performance Metrics</b> N/A</p>														<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>Title:</b> Breast Cancer Stamp Proceeds	0.602	-	-	<b>Description:</b> This is a Congressional Interest Item.				<b>FY 2013 Accomplishments:</b> Breast Cancer Stamp Proceeds				<b>Accomplishments/Planned Programs Subtotals</b>	0.602	-	-
	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>																													
<b>Title:</b> Breast Cancer Stamp Proceeds	0.602	-	-																													
<b>Description:</b> This is a Congressional Interest Item.																																
<b>FY 2013 Accomplishments:</b> Breast Cancer Stamp Proceeds																																
<b>Accomplishments/Planned Programs Subtotals</b>	0.602	-	-																													



**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army										<b>Date:</b> March 2014																																																						
<b>Appropriation/Budget Activity</b> 2040 / 3					<b>R-1 Program Element (Number/Name)</b> PE 0603002A / MEDICAL ADVANCED TECHNOLOGY				<b>Project (Number/Name)</b> 97T / NEUROTOXIN EXPOSURE TREATMENT																																																							
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015 Base</b>	<b>FY 2015 OCO #</b>	<b>FY 2015 Total</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>Cost To Complete</b>	<b>Total Cost</b>																																																				
97T: NEUROTOXIN EXPOSURE TREATMENT	-	15.979	16.000	-	-	-	-	-	-	-	-	-																																																				
<p># The FY 2015 OCO Request will be submitted at a later date.</p> <p><b>A. Mission Description and Budget Item Justification</b> Congressional Interest Item funding for Neurotoxin Exposure Treatment.</p> <p><b>B. Accomplishments/Planned Programs (\$ in Millions)</b></p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th><b>FY 2013</b></th> <th><b>FY 2014</b></th> <th><b>FY 2015</b></th> </tr> </thead> <tbody> <tr> <td><b>Title:</b> Peer-Reviewed Neurotoxin Exposure Treatment Parkinsons Research Program</td> <td align="right">15.979</td> <td align="right">16.000</td> <td align="center">-</td> </tr> <tr> <td colspan="4"><b>Description:</b> This congressionally directed project conducts research for the Neurotoxin Exposure Treatment Parkinsons Research Program.</td> </tr> <tr> <td colspan="4"><b>FY 2013 Accomplishments:</b> Neurotoxin Exposure Treatment Parkinsons Research Program</td> </tr> <tr> <td colspan="4"><b>FY 2014 Plans:</b> Neurotoxin Exposure Treatment Parkinsons Research Program</td> </tr> <tr> <td align="right" colspan="2"><b>Accomplishments/Planned Programs Subtotals</b></td> <td align="right">15.979</td> <td align="right">16.000</td> </tr> <tr> <td align="center" colspan="4"><b>C. Other Program Funding Summary (\$ in Millions)</b></td> </tr> <tr> <td colspan="4">N/A</td> </tr> <tr> <td colspan="4"><b>Remarks</b></td> </tr> <tr> <td colspan="4"><b>D. Acquisition Strategy</b></td> </tr> <tr> <td colspan="4">N/A</td> </tr> <tr> <td colspan="4"><b>E. Performance Metrics</b></td> </tr> <tr> <td colspan="4">N/A</td> </tr> </tbody> </table>														<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>Title:</b> Peer-Reviewed Neurotoxin Exposure Treatment Parkinsons Research Program	15.979	16.000	-	<b>Description:</b> This congressionally directed project conducts research for the Neurotoxin Exposure Treatment Parkinsons Research Program.				<b>FY 2013 Accomplishments:</b> Neurotoxin Exposure Treatment Parkinsons Research Program				<b>FY 2014 Plans:</b> Neurotoxin Exposure Treatment Parkinsons Research Program				<b>Accomplishments/Planned Programs Subtotals</b>		15.979	16.000	<b>C. Other Program Funding Summary (\$ in Millions)</b>				N/A				<b>Remarks</b>				<b>D. Acquisition Strategy</b>				N/A				<b>E. Performance Metrics</b>				N/A			
	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>																																																													
<b>Title:</b> Peer-Reviewed Neurotoxin Exposure Treatment Parkinsons Research Program	15.979	16.000	-																																																													
<b>Description:</b> This congressionally directed project conducts research for the Neurotoxin Exposure Treatment Parkinsons Research Program.																																																																
<b>FY 2013 Accomplishments:</b> Neurotoxin Exposure Treatment Parkinsons Research Program																																																																
<b>FY 2014 Plans:</b> Neurotoxin Exposure Treatment Parkinsons Research Program																																																																
<b>Accomplishments/Planned Programs Subtotals</b>		15.979	16.000																																																													
<b>C. Other Program Funding Summary (\$ in Millions)</b>																																																																
N/A																																																																
<b>Remarks</b>																																																																
<b>D. Acquisition Strategy</b>																																																																
N/A																																																																
<b>E. Performance Metrics</b>																																																																
N/A																																																																

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Army										Date: March 2014		
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 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
FH4: Force Health Protection - Adv Tech Dev	-	1.488	1.661	1.692	-	1.692	1.276	1.340	1.788	1.880	-	-
# The FY 2015 OCO Request will be submitted at a later date.												
A. Mission Description and Budget Item Justification												
This project matures, 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. These databases and systems enhance the DoD's 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) and 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.												
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 2013	FY 2014	FY 2015	
Title: Health Research									1.488	1.661	1.692	
Description: This effort supports validation of interventions from the Millennium Cohort study (a prospective health project in military Service members designed to evaluate the long-term health effects of military service, including deployments), validation of biomarkers of exposure, methods to detect environmental contamination and toxic exposure, and validation of thoracic (chest) injury prediction models of blast exposure.												
FY 2013 Accomplishments:												
Matured strategic findings from studies that support policy formation and guide further research to promote the longer-term physical and mental health of the Force. This work lead to a greater appreciation of post-traumatic stress disorder for the senior												

# UNCLASSIFIED

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army		<b>Date:</b> March 2014	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / MEDICAL ADVANCED TECHNOLOGY	<b>Project (Number/Name)</b> FH4 / Force Health Protection - Adv Tech Dev	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>
military leadership and helped mitigate the physical and psychological effects of military service, protecting the Warfighter from potentially devastating consequences.			
<b>FY 2014 Plans:</b> Assess modifiable behaviors and emerging health concerns among Service members using survey data and other health outcome measures and assess validity of health screening instruments/surveys and other health measures. These data lead to a greater understanding of the impact of physical and mental health issues for Service members. This effort potentially provides screening and preventive strategies to decrease negative health consequences and inform DoD policies.			
<b>FY 2015 Plans:</b> Will assess modifiable behaviors and those resilience factors that protect Service Members from adverse mental or physical health outcomes. Will assess the economic burden of negative coping behaviors such as alcohol and tobacco use. This effort will provide screening factors to assess military Family well-being and resilience.			
<b>Accomplishments/Planned Programs Subtotals</b>		1.488	1.661
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			

**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army										<b>Date:</b> March 2014																										
<b>Appropriation/Budget Activity</b> 2040 / 3					<b>R-1 Program Element (Number/Name)</b> PE 0603002A / MEDICAL ADVANCED TECHNOLOGY				<b>Project (Number/Name)</b> MM2 / MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)																											
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015 Base</b>	<b>FY 2015 OCO #</b>	<b>FY 2015 Total</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>Cost To Complete</b>	<b>Total Cost</b>																								
MM2: MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)	-	7.076	8.000	-	-	-	-	-	-	-	-	-																								
<p># The FY 2015 OCO Request will be submitted at a later date.</p> <p><b>A. Mission Description and Budget Item Justification</b> Congressional Interest Item funding for Medical Advanced Technology Initiatives.</p> <p><b>B. Accomplishments/Planned Programs (\$ in Millions)</b></p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th><b>FY 2013</b></th> <th><b>FY 2014</b></th> <th><b>FY 2015</b></th> </tr> </thead> <tbody> <tr> <td><b>Title:</b> Military Burn Trauma Research Program</td> <td align="right">7.076</td> <td align="right">8.000</td> <td align="center">-</td> </tr> <tr> <td><b>Description:</b> This is a Congressional Interest Item.</td> <td></td> <td></td> <td></td> </tr> <tr> <td><b>FY 2013 Accomplishments:</b> Military Burn Trauma Research Program</td> <td></td> <td></td> <td></td> </tr> <tr> <td><b>FY 2014 Plans:</b> Military Burn Trauma Research Program</td> <td></td> <td></td> <td></td> </tr> <tr> <td align="right" colspan="2"><b>Accomplishments/Planned Programs Subtotals</b></td> <td align="right">7.076</td> <td align="right">8.000</td> </tr> </tbody> </table> <p><b>C. Other Program Funding Summary (\$ in Millions)</b> N/A</p> <p><b>Remarks</b></p> <p><b>D. Acquisition Strategy</b> N/A</p> <p><b>E. Performance Metrics</b> N/A</p>														<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>Title:</b> Military Burn Trauma Research Program	7.076	8.000	-	<b>Description:</b> This is a Congressional Interest Item.				<b>FY 2013 Accomplishments:</b> Military Burn Trauma Research Program				<b>FY 2014 Plans:</b> Military Burn Trauma Research Program				<b>Accomplishments/Planned Programs Subtotals</b>		7.076	8.000
	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>																																	
<b>Title:</b> Military Burn Trauma Research Program	7.076	8.000	-																																	
<b>Description:</b> This is a Congressional Interest Item.																																				
<b>FY 2013 Accomplishments:</b> Military Burn Trauma Research Program																																				
<b>FY 2014 Plans:</b> Military Burn Trauma Research Program																																				
<b>Accomplishments/Planned Programs Subtotals</b>		7.076	8.000																																	

**UNCLASSIFIED**

Exhibit R-2A, RDT&E Project Justification: PB 2015 Army										Date: March 2014		
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 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
MM3: Warfighter Medical Protection & Performance	-	9.467	11.407	17.991	-	17.991	19.154	19.273	19.057	19.328	-	-
# The FY 2015 OCO Request will be submitted at a later date.												
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 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 three main thrust areas are (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. 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 2013	FY 2014	FY 2015	
Title: Physiological (human physical and biochemical functions) Health and Environmental Protection (Sleep Research/ Environmental Monitoring)									1.555	1.573	1.698	
Description: This effort supports and matures laboratory products, nutritional interventions, and decision aids for the validation of physiological (human physical and biochemical functions) 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 FY2013-2014, and also supports capability demonstrations in the area of decreasing Soldier physical burden in FY2013-2014.												
FY 2013 Accomplishments:												

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Army			Date: March 2014		
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>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<p>Evaluated real-time 'thermal strain monitoring and management' system in Brigade Modernization exercise or similar operationally relevant field environment and identified model factors accounting for individual differences in vulnerability to sleep loss and model stimulant countermeasure effects. These results serve to manage thermal strain and sleep loss in real-time.</p> <p><b>FY 2014 Plans:</b> Demonstrate the effectiveness of nutritional interventions for facilitating wound healing and supporting immune function; demonstrate real-time physiological status monitoring systems for operational use in-theater; enhance injury prediction algorithms for incorporation into wearable sensor systems; and allow the prediction and prevention of physical injury and health outcomes.</p> <p><b>FY 2015 Plans:</b> Will perform field-studies to demonstrate the efficacy of nutritional interventions for optimizing Warrior recovery from physical and mental injury. Will validate algorithms and mathematical models capable of predicting cognitive status and monitoring recovery and healing from physical injury.</p>					
<p><b>Title:</b> Environmental Health and Protection - Physiological (human physical and biochemical functions) Awareness Tools and Warrior Sustainment in Extreme Environments</p> <p><b>Description:</b> This effort supports and matures 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 in FY2013-2014.</p> <p><b>FY 2013 Accomplishments:</b> Developed refined novel hydration sensor technologies with high (80-95%) diagnostic accuracy. This serves to reduce the incidence of electrolyte-related injury among Warfighters due to diarrheal disease incidence or exertion-based dehydration.</p> <p><b>FY 2014 Plans:</b> Determine the prototype noninvasive hydration sensor technologies that meet requirements for clinical precision and reliability. This technology is used to determine Warrior hydration status and inform appropriate clinical intervention and will reduce the incidence of heat injuries among Warriors.</p> <p><b>FY 2015 Plans:</b> Will conduct a feasibility study to determine saliva biomarker (physiological indicator of a specific biological state) panel that will distinguish levels of dehydration in exertional exercise in order to prevent heat injury. Will validate organ damage biomarkers to clinical measures in heat stroke patients. Will determine efficacy of drug treatments for heat injury and heat stroke recovery. Will provide strategies for localized heating to optimize hand and finger dexterity for specific military tasks. Will exploit nanomaterials (materials smaller than a one tenth of a micrometer in at least one dimension) for developing advanced focused heating</p>			1.005	1.043	2.356

# UNCLASSIFIED

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army		<b>Date:</b> March 2014		
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / MEDICAL ADVANCED TECHNOLOGY	<b>Project (Number/Name)</b> MM3 / Warfighter Medical Protection & Performance		
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
approaches to prevent nonfreezing cold injury. Will evaluate the efficacy of new pharmaceuticals to prevent acute mountain sickness and improve work performance at high altitude.				
<b>Title:</b> Injury Prevention and Reduction (Physical Performance Enhancement) <b>Description:</b> This effort supports and validates injury prediction tools for brain, spine, and thoracic (chest) injury from blast, blunt, and ballistic impact. 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 in FY2013-2014. <b>FY 2013 Accomplishments:</b> Validated the feasibility of using physiologically based injury models to interpret sensors and real-time exposure and response algorithms of injury risk and performance status following blast and blunt force thoracic trauma, including penetration wounding, and pulmonary injuries from blast and blunt trauma caused by ballistic impact. <b>FY 2014 Plans:</b> Upgrade the blast, blunt trauma, and inhalation performance decrement software to incorporate extreme environmental stressors and mature musculoskeletal models for predicting physical performance injury and health outcomes for military-relevant tasks, accounting for individual variations, equipment, and environmental factors. <b>FY 2015 Plans:</b> Will provide medical standards for protection against hearing and vestibular injuries and ensure compatibility with military operations and maintenance of Warfighter situational awareness. Will develop and validate improved sensory system injury countermeasures. Will develop and validate computational models to predict the effects of the primary blast wave on the face and eyes. Will 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.		3.848	5.211	3.762
<b>Title:</b> Psychological Health and Resilience <b>Description:</b> This effort supports and validates neurocognitive assessment and brain injury detection methods; and validates tools and preclinical methods to treat post-traumatic stress disorder in a military population. This effort supports Technology Enabled Capability Demonstration 7.d, Brain In Combat, in FY2013-2014. <b>FY 2013 Accomplishments:</b> Developed guidance on pharmacological interventions to improve psychological and neurophysiological functioning post-concussion; conducted studies to develop and validate reliable metrics for identification, time course, and prospective neurocognitive/neurological effects of mild Traumatic Brain Injury (mTBI); convened working group panels to develop and execute		3.059	3.580	10.175

# UNCLASSIFIED

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army		<b>Date:</b> March 2014	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>MEDICAL ADVANCED TECHNOLOGY</i>	<b>Project (Number/Name)</b> MM3 / <i>Warfighter Medical Protection &amp; Performance</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>
<p>strategic findings from studies that support policy formation; and designed a strategic research approach to promote the longer-term physical and mental health of the Force.</p> <p><b>FY 2014 Plans:</b>            Demonstrate the utility of magnetoencephalography, a cutting-edge imaging technique for the brain, to differentiate post-traumatic stress disorder from brain injury following a post-concussion event and the utility of circulating blood biomarkers for effective acute assessment of brain injury post-concussion symptoms and demonstrate whether neurocognitive testing can accurately inform assessment of the brain injury following a post-concussion event. These efforts lead to more effective assessments of Warriors and facilitate improved strategies for appropriate care and identify better treatment modalities for brain injury following a post-concussion event.</p> <p><b>FY 2015 Plans:</b>            Will provide guidance on the utilization of sleep measures to aid in the diagnosis, prognosis, and monitoring of recovery from a post-concussion event. Will 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. Will validate algorithms that predict concussion injury and incorporate these into currently available blast-wave concussion sensor systems. Will evaluate the efficacy of bright light therapy for PTSD treatment. Will determine the gender-relevant signatures of PTSD and the changes in biomarker levels associated with PTSD onset during deployment.</p>			
<b>Accomplishments/Planned Programs Subtotals</b>		9.467	11.407
<b>C. Other Program Funding Summary (\$ in Millions)</b>			
N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b>			
N/A			
<b>E. Performance Metrics</b>			
N/A			