Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Army											DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 3: *Advanced Technology Development (ATD)*					R-1 ITEM NOMENCLATURE PE 0603002A: *MEDICAL ADVANCED TECHNOLOGY*							
COST ($ in Millions)	**All Prior Years**	**FY 2012**	**FY 2013#**	**FY 2014 Base**	**FY 2014 OCO ##**	**FY 2014 Total**	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**	**Cost To Complete**	**Total Cost**
Total Program Element	-	101.655	69.580	62.032	-	62.032	65.167	65.900	64.619	66.367	Continuing	Continuing
810: *Ind Base Id Vacc&Drug*	-	18.234	19.574	17.413	-	17.413	17.022	16.000	13.779	15.374	Continuing	Continuing
814: *NEUROFIBROMATOSIS*	-	12.780	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
840: *Combat Injury Mgmt*	-	37.561	37.396	31.544	-	31.544	32.485	33.696	34.459	34.695	Continuing	Continuing
945: *BREAST CANCER STAMP PROCEEDS*	-	0.695	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
97T: *NEUROTOXIN EXPOSURE TREATMENT*	-	15.975	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
FH4: *Force Health Protection - Adv Tech Dev*	-	1.493	1.690	1.662	-	1.662	1.692	1.730	1.799	1.788	Continuing	Continuing
MM2: *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*	-	5.991	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
MM3: *Warfighter Medical Protection & Performance*	-	8.926	10.920	11.413	-	11.413	13.968	14.474	14.582	14.510	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 OCO Request will be submitted at a later date

Note

FY14 funding decrease to support higher priority efforts.

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. 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

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) 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.

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 Pr

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B. Program Change Summary ($ in Millions)	**FY 2012**	**FY 2013**	**FY 2014 Base**	**FY 2014 OCO**	**FY 2014 Total**
Previous President's Budget	102.810	69.580	70.759	-	70.759
Current President's Budget	101.655	69.580	62.032	-	62.032
Total Adjustments	-1.155	0.000	-8.727	-	-8.727
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	0.674	-			
• SBIR/STTR Transfer	-1.829	-			
• Adjustments to Budget Years	-	-	-8.727	-	-8.727

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COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
810: *Ind Base Id Vacc&Drug*	-	18.234	19.574	17.413	-	17.413	17.022	16.000	13.779	15.374	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

This project maturates and demonstrates FDA-regulated medical countermeasures such as drugs, vaccines, and diagnostic 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 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 EPA.

Research conducted in this project focuses on the following five areas:
(1) Drugs to Prevent/Treat Parasitic (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 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.

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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 Walter Reed Army Institute of Research, Silver Spring, MD, and its overseas laboratories; USAMRIID, Fort Detrick, MD; and the Navel 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 2012	FY 2013	FY 2014
Title: Drugs to Prevent/Treat Parasitic Diseases	2.287	2.932	2.247
Description: 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. ***FY 2012 Accomplishments:*** Initiated safety and effectiveness studies in human volunteers on the most promising candidate identified from preclinical studies. ***FY 2013 Plans:*** Evaluate effectiveness of new anti-parasitic drugs through testing in human populations exposed to malaria and leishmania infections. ***FY 2014 Plans:*** Will assess effectiveness of new and refined anti-parasitic drugs through testing in human populations exposed to malaria and leishmania infections world-wide.			
Title: Vaccines for Prevention of Malaria	4.804	5.556	5.401
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 2012 Accomplishments:*** Formulated new candidate vaccines against Plasmodium falciparum and Plasmodium vivax malaria and tested them in uninfected adults for safety, immunogenicity (ability to produce an immune response), and effectiveness; further tested the most promising			

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
vaccine candidates in adults and children in larger test populations where malaria occurs naturally; and transferred vaccine candidate to the Advanced Development program. ***FY 2013 Plans:*** Conduct clinical trials of multiple types of vaccines in human populations using laboratory-based human challenge model. Then, for promising candidates, optimize administration for testing in human populations naturally exposed to malaria. If a successful candidate is identified, transition to Advanced Development. ***FY 2014 Plans:*** Will conduct clinical trials of new formulations of vaccine candidates to assess safety and effectiveness in humans and will assess vaccine performance for suitability 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 diarrhea (E. coli, Campylobacter, and Shigella (a significant threat during initial deployments) and meningococcal vaccine candidates (a threat to trainees, deployed troops, and military families) for testing in human subjects. Data packages are prepared, as required for FDA approval, and testing is conducted in human subjects. ***FY 2012 Accomplishments:*** Conducted human trials of live attenuated Shigella vaccine and E. coli vaccine to determine their effectiveness, and completed transfer of meningococcal vaccine technology to commercial partner. ***FY 2013 Plans:*** Conduct second human clinical trial for E. coli vaccines to determine the best candidate vaccine, route of administration, and dosage; conduct additional human clinical trials on best Shigella vaccine based on FY2012 human trial results; and evaluate results of Campylobacter clinical trial conducted in FY2012. ***FY 2014 Plans:*** Will produce best vaccine candidates by using Good Manufacturing Practices developed by the FDA; will conduct safety trials of multiple vaccine candidates against three diarrheal pathogens (infectious agents) of interest (Shigella, Campylobacter, and E. coli) in human volunteers.	7.438	5.508	5.277
Title: Viral Disease Threats ***Description:*** 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-	1.787	3.359	2.756

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
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. ***FY 2012 Accomplishments:*** Further developed the hantavirus vaccine with support of a commercial partner to include evaluation of vaccine delivery methods to improve effectiveness and safety and transitioned to Advanced Development program. ***FY 2013 Plans:*** Demonstrate 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; conduct further clinical testing of dengue vaccine candidates; further develop 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 prepare and conduct safety studies in human volunteers with new HIV vaccine candidates at multiple sites worldwide. ***FY 2014 Plans:*** Will evaluate the alternative strategies to deliver vaccine candidates in human muscle and skin to develop a needle-free injection; will 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 will further evaluate human safety and effectiveness of best vaccine candidates against all dengue types present worldwide.			
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 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 arthropods (animals without a backbone with segmented bodies and jointed limbs, such as a scorpion, crab, or centipede). ***FY 2012 Accomplishments:*** Completed the evaluation of repellent products; assisted the commercial partners in fielding FDA-approved rapid human diagnostics (point-of-care tests) for Q-fever and evaluated a field detection device to detect Japanese encephalitis and other pathogens transmitted by arthropods (animals without a backbone with segmented bodies and jointed limbs, such as a scorpion, crab, or centipede) in collaboration with commercial partner. ***FY 2013 Plans:*** Complete 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; complete field evaluations on prototype rapid diagnostic kits developed for the detection of selected vector-borne pathogens (pathogens	1.918	2.219	1.732

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
transmitted by insects, such as malaria, leishmania, and dengue virus); complete the development of an enteric assay to transition the assay to Advanced Development; and complete field evaluations and FDA-required 510K clearance on the Dengue Rapid Diagnostic Device. ***FY 2014 Plans:*** Will 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; will conduct field evaluation of the new alternate repellent products in overseas field locations; and will evaluate the NGDS assays (tests) for use in diagnosing pathogens (infectious agents) in humans.			
Accomplishments/Planned Programs Subtotals	18.234	19.574	17.413

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

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COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
814: *NEUROFIBROMATOSIS*	-	12.780	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Neurofibromatosis research.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Neurofibromatosis (NF) Research Program	12.780	0.000	0.000
Description: This congressionally directed project conducted research on Neurofibromatosis (NF).			
FY 2012 Accomplishments: This congressionally directed project conducted research on Neurofibromatosis (NF).			
Accomplishments/Planned Programs Subtotals	12.780	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

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COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
840: *Combat Injury Mgmt*	-	37.561	37.396	31.544	-	31.544	32.485	33.696	34.459	34.695	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 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; 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.

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Damage Control Resuscitation	11.159	9.722	7.118
Description: 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). ***FY 2012 Accomplishments:*** Initiated limited clinical studies of coagulation factor and platelet function in burn patients; conducted studies of acute coagulopathy (clotting or bleeding disorder) of traumatic shock; and evaluated currently available blood products in a large animal (pig) model. ***FY 2013 Plans:*** Continue coagulation (blood clotting) factor and platelet function studies of ways to stop bleeding and study the use of compounds to reduce inflammation as a therapy for bleeding caused by trauma. ***FY 2014 Plans:*** Will 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; will 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 will validate an improved blood platelet storage technology for far-forward use.			
Title: Combat Trauma Therapies	3.466	5.658	5.173
Description: 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. This effort includes neuroprotective research -- funding in this area transitioned to Traumatic Brain Injury in FY2012. ***FY 2012 Accomplishments:*** Conducted studies in wound healing, as well as skin, muscle, and bone repair; transferred skin and muscle work to more relevant animal models and continued in-house human trials; FY2012 - work in neuroprotection research transitioned to Traumatic Brain Injury. ***FY 2013 Plans:*** Conduct small-scale clinical trials for most promising therapies for loss of large volumes of muscle and wound healing agents. ***FY 2014 Plans:***			

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Will transition biofilm diagnostics, drugs that disrupt biofilm formation, and therapies to clinical evaluation and will 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.			
Title: Traumatic Brain Injury ***Description:*** 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. This research area started in FY2012. In FY2013 and FY2014, this effort supports Technology-Enabled Capability Demonstration 7.d, Brain in Combat. ***FY 2012 Accomplishments:*** Sought to complete the FDA effectiveness study of the candidate neuroprotective drug for treatment of TBI and completed the pivotal trial for a bench-top assay for use in hospitals using candidate biomarkers for the detection of TBI; made preparation for transition to Advanced Development; continued development of a smaller, deployable diagnostic device for brain trauma as well as a hand held version; and evaluated progesterone (steroid hormone) and nitrite as therapeutic interventions for blast injury. ***FY 2013 Plans:*** Identify combination therapeutics for Advanced Development/clinical trials for TBI that substantially mitigate or reduce TBI-induced non-convulsive seizures and brain damage. ***FY 2014 Plans:*** Will continue/finish 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.	4.164	3.255	3.398
Title: Combat Critical Care Engineering ***Description:*** This effort supports diagnostic and therapeutic medical devices, algorithms, software, and data-processing systems for resuscitation, stabilization, and life support. ***FY 2012 Accomplishments:*** Began collection of continuous waveform data (output from vital signs monitors) in burn and trauma patients with blood loss to refine algorithm and evaluated commercially viable measurement systems and novel remote triage devices (both wear-and-forget and stand-off devices) for effectiveness and specificity to blood loss. ***FY 2013 Plans:***	2.974	3.973	4.350

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Start 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 transition vital signs technology to Advanced Development for further test and evaluation, FDA licensure, and for fielding. ***FY 2014 Plans:*** Will seek FDA clearance for advanced algorithms that measure tissue blood flow, metabolism, and oxygenation and will evaluate ventilation strategies to improve neurologic (brain) status in casualties (those injured) with TBI.			
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 2012 Accomplishments:*** Continued preclinical studies on novel drug delivery, diagnostic and/or tissue repair strategies for eye injury, as well as initial clinical studies of vision rehabilitation strategies; continued preclinical and initial clinical studies of strategies for maxillofacial reconstruction, including wound healing control and tissue engineering/regeneration techniques, to restore facial features; began a pilot clinical trial of a drug that reduces the spread of burn damage; finished preclinical research on engineered implants; started a pilot clinical trial on bone regeneration using scaffold and stem cell technologies; and continued an ongoing clinical trial in muscle regeneration. ***FY 2013 Plans:*** Continue to develop drug delivery and diagnostic and tissue repair strategies, including stem cell therapies for traumatic eye injury; continue development and standardization of animal models to assess soft and hard tissue regeneration technologies; continue studies of burn, scarless wound, soft tissue, and bone repair strategies; continue development and testing of stem cell therapies and scaffolds (tissue-engineered grafts) in animal models; and continue 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. ***FY 2014 Plans:*** Will evaluate the preclinical safety and effectiveness of promising drug delivery, diagnostic, tissue repair, and/or treatment strategies for traumatic eye injury; will continue to conduct clinical research for rehabilitation strategies for traumatic eye injury; will incrementally build upon past successes to develop novel drug delivery, diagnostic, reconstructive, and regenerative strategies; will utilize and refine cell-based therapies (including stem cells) and tissue scaffolds (tissue-engineered grafts) to assess soft	10.634	10.588	9.328

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603002A: *MEDICAL ADVANCED TECHNOLOGY*	PROJECT 840: *Combat Injury Mgmt*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
and hard tissue repair and regeneration safety and effectiveness; and will also build upon promising approaches from FY2013 by continuing the 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.			
Title: Under Body Blast Injury Assessment ***Description:*** This 1-year effort supports research to enable the Live-Fire Test and Evaluation (LFT&E) community to conduct realistic survivability testing of ground-combat vehicles subjected to underbody blast (UBB) threats, with a primary emphasis on assessing potential occupant casualties, as well as to enable the development and testing of improved occupant protection systems. UBB creates injurious forces on occupants of ground-combat vehicles that are more violent and that act in directions not normally encountered in civilian automotive accidents. Injury prediction tools that were developed to assess occupant safety in automobile crashes are not adequate for assessing occupant survivability in ground-combat vehicles exposed to UBB threats. Accurately predicting the spectrum of injuries caused by UBB forces in live-fire tests of ground-combat vehicles presents a unique challenge for the Department of Defense (DoD). A UBB medical research program is being initiated to understand the human tolerance limits and injury mechanisms needed to accurately predict injuries to ground-combat vehicle occupants caused by UBB events. ***FY 2012 Accomplishments:*** Initiated research to develop biomedically valid UBB human tolerance limits and injury prediction tools for supporting the development of DoD blast injury prevention standards for survivability assessments and protection systems development and accelerated development and integration of human tolerance limits and injury prediction tools to enhance the LFT&E communitys ability to accurately assess ground-combat vehicle occupant survivability in UBB events.	5.164	0.000	0.000
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 2013 Plans:*** Funding 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. ***FY 2014 Plans:*** 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.	0.000	4.200	2.177
Accomplishments/Planned Programs Subtotals	37.561	37.396	31.544

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
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C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603002A: *MEDICAL ADVANCED TECHNOLOGY*	PROJECT 945: *BREAST CANCER STAMP PROCEEDS*	

COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
945: *BREAST CANCER STAMP PROCEEDS*	-	0.695	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 OCO Request will be submitted at a later date

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 2012	FY 2013	FY 2014
Title: Breast Cancer Stamp Proceeds	0.695	0.000	0.000
Description: This is a Congressional Interest Item.			
FY 2012 Accomplishments: This is a Congressional Interest Item.			
Accomplishments/Planned Programs Subtotals	0.695	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603002A: *MEDICAL ADVANCED TECHNOLOGY*	PROJECT 97T: *NEUROTOXIN EXPOSURE TREATMENT*	

COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
97T: *NEUROTOXIN EXPOSURE TREATMENT*	-	15.975	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Neurotoxin Exposure Treatment.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Peer-Reviewed Neurotoxin Exposure Treatment Parkinsons Research Program	15.975	0.000	0.000
Description: This congressionally directed project conducts research for the Neurotoxin Exposure Treatment Parkinsons Research Program. ***FY 2012 Accomplishments:*** Conducted research for the Neurotoxin Exposure Treatment Parkinsons Research Program.			
Accomplishments/Planned Programs Subtotals	15.975	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603002A: *MEDICAL ADVANCED TECHNOLOGY*	PROJECT FH4: *Force Health Protection - Adv Tech Dev*	

COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
FH4: *Force Health Protection - Adv Tech Dev*	-	1.493	1.690	1.662	-	1.662	1.692	1.730	1.799	1.788	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 OCO Request will be submitted at a later date

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. 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.

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Health Research	1.493	1.690	1.662
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 injury prediction models of blast exposure.			

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
FY 2012 Accomplishments: Validated potential intervention strategies for reduction of mental health symptoms and factors associated with suicide, with a goal to reduce the suicide rate, and validated sensor components to include whole-body acceleration (tertiary blast injury) and headform acceleration (TBI). ***FY 2013 Plans:*** Mature 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 will lead to a greater appreciation of post-traumatic stress disorder for the senior military leadership and will help mitigate the physical and psychological effects of military service, protecting the Warfighter from potentially devastating consequences. ***FY 2014 Plans:*** Will assess modifiable behaviors and emerging health concerns among Service members using survey data and other health outcome measures and will assess validity of health screening instruments/surveys and other health measures. These data will lead to a greater understanding of the impact of physical and mental health issues for Service members. This effort will potentially provide screening and preventive strategies to decrease negative health consequences and inform DoD polices.			
Accomplishments/Planned Programs Subtotals	1.493	1.690	1.662

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603002A: *MEDICAL ADVANCED TECHNOLOGY*	PROJECT MM2: *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*	

COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
MM2: *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*	-	5.991	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Medical Advanced Technology Initiatives.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Military Burn Trauma Research Program. ***Description:*** This is a Congressional Interest Item. ***FY 2012 Accomplishments:*** Military Burn Trauma Research Program.	5.991	0.000	0.000
Accomplishments/Planned Programs Subtotals	5.991	0.000	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603002A: *MEDICAL ADVANCED TECHNOLOGY*	PROJECT MM3: *Warfighter Medical Protection & Performance*	

COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
MM3: *Warfighter Medical Protection & Performance*	-	8.926	10.920	11.413	-	11.413	13.968	14.474	14.582	14.510	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 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.

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Physiological Health and Environmental Protection (Sleep Research/Environmental Monitoring)	1.534	1.597	1.573
Description: This effort supports and maturates laboratory products, 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 FY2013-2014, and also supports Technology-Enabled Capability Demonstration 2.a, Overburdened-Physical Burden in FY2013-2014.			
FY 2012 Accomplishments:			

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Completed field studies of the heat strain decision-aid with the U.S. Army Ranger School to reduce the risk of heat injuries during training and validated a computational model for predicting performance affected by chronic sleep restriction in the operational environment. ***FY 2013 Plans:*** Evaluate real-time 'thermal strain monitoring and management' system in Brigade Modernization exercise or similar operationally relevant field environment and identify 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. ***FY 2014 Plans:*** Will demonstrate the effectiveness of nutritional interventions for facilitating wound healing and supporting immune function; will demonstrate real-time physiological status monitoring systems for operational use in-theater; will enhance injury prediction algorithms for incorporation into wearable sensor systems; and will allow the prediction and prevention of physical injury and health outcomes.			
Title: Environmental Health and Protection - Physiological 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 Technology-Enabled Capability Demonstration 2.a, Overburdened Physical Burden in FY2013-2014. ***FY 2012 Accomplishments:*** Validated reference values for non-invasive hydration status markers and transitioned non-invasive hydration assessment sensors to the advanced development program. ***FY 2013 Plans:*** Refine novel hydration sensor technologies with a goal of achieving high (80-95%) diagnostic accuracy. This serves to reduce the incidence of electrolyte-related injury among Warfighters. ***FY 2014 Plans:*** Will determine the prototype noninvasive hydration sensor technologies that meet requirements for clinical precision and reliability. This technology will be used to determine Warrior hydration status and will inform appropriate clinical intervention and will reduce the incidence of heat injuries among Warriors.	1.480	1.726	1.043
Title: Injury Prevention and Reduction (Physical Performance Enhancement) ***Description:*** This effort supports and validates injury prediction tools for brain, spine, and thoracic injury from blast, blunt, and ballistic impact. This effort supports Technology-Enabled Capability Demonstration 1.b, Force Protection--Soldier and Small	3.453	4.392	5.217

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Unit in FY2013-2014, and also supports Technology-Enabled Capability Demonstration 2.a, Overburdened-Physical Burden in FY2013-2014. ***FY 2012 Accomplishments:*** Validated software that accounts for the effects of clothing and body armor on the body following blast; validated software to estimate lung, heart, and rib injury from blunt trauma caused by debris impact (secondary blast injury); and validated the effectiveness of selected elements of neurosensory performance assessment batteries. ***FY 2013 Plans:*** Validate 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. ***FY 2014 Plans:*** Will upgrade the blast, blunt trauma, and inhalation performance decrement software to incorporate extreme environmental stressors and will mature musculoskeletal models for predicting physical performance injury and health outcomes for military-relevant tasks, accounting for individual variations, equipment, and environmental factors.			
Title: Psychological Health and Resilience ***Description:*** 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. ***FY 2012 Accomplishments:*** Determined effectiveness of various treatment modalities (e.g., occupational therapy, counseling, etc.) and validated screening/scoring guidelines for revisions to the Post-Deployment Health Assessment and the Post-Deployment Health Reassessment. ***FY 2013 Plans:*** Develop guidance on pharmacological interventions to improve psychological and neurophysiological functioning post-concussion; conduct studies to develop and validate reliable metrics for identification, time course, and prospective neurocognitive/neurological effects of mild Traumatic Brain Injury (mTBI); convene working group panels to develop and execute strategic findings from studies that support policy formation; and design a strategic research approach to promote the longer-term physical and mental health of the Force. ***FY 2014 Plans:***	2.459	3.205	3.580

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Will 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 will demonstrate whether neurocognitive testing can accurately inform assessment of the brain injury following a post-concussion event. These efforts will lead to more effective assessment of Warriors and will facilitate improved strategies for appropriate care and will identify better treatment modalities for brain injury following a post-concussion event.			
Accomplishments/Planned Programs Subtotals	8.926	10.920	11.413

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.