Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Army											DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*					R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL 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	-	104.190	107.891	93.340	-	93.340	83.115	81.902	85.694	89.953	Continuing	Continuing
869: *Warfighter Health Prot & Perf Stnds*	-	37.910	38.907	34.728	-	34.728	33.230	30.317	30.656	31.482	Continuing	Continuing
870: *Dod Med Def Ag Inf Dis*	-	16.842	18.987	19.072	-	19.072	20.828	22.500	23.725	25.618	Continuing	Continuing
873: *HIV Exploratory Rsch*	-	9.117	8.986	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
874: *Cbt Casualty Care Tech*	-	16.837	19.821	18.271	-	18.271	16.829	17.693	18.788	20.119	Continuing	Continuing
FH2: *Force Health Protection - Applied Research*	-	8.888	6.279	6.316	-	6.316	7.436	6.523	7.568	7.686	Continuing	Continuing
VB4: *System Biology And Network Science Technology*	-	4.596	4.802	4.839	-	4.839	4.792	4.869	4.957	5.048	Continuing	Continuing
VJ4: *Suicide Prevention/ Mitigation*	-	10.000	10.109	10.114	-	10.114	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

Note

FY14 decrease attributed to transfer of HIV research funding from RDT&E,Army to RDT&E Defense-wide and other realignments to fund higher priority efforts.

A. Mission Description and Budget Item Justification

This program element (PE) supports application of knowledge gained through basic research to refine drugs, vaccines, medical devices, diagnostics, medical practices/ procedures, and other preventive measures essential to the protection and sustainment of Warfighter health. Research is conducted in five principal areas: Combat Casualty Care; Military Operational Medicine; Military Relevant Infectious Diseases, including human immunodeficiency virus (HIV); Clinical and Rehabilitative Medicine; and Systems Biology/Network Sciences. Research is funded in seven projects.

Project 869 refines knowledge and technologies on screening tools and preventive measures for post-traumatic stress disorder and mild traumatic brain injuries, physiological monitors, and interventions to protect Soldiers from injuries resulting from operational stress, and exposure to hazardous environments and materials. Also conducts research on medically valid testing devices and predictive models used for the refinement of Soldier protective equipment. This project is being coordinated with the Defense Health Program.

Project 870 designs and refines medical diagnostic devices, drugs, and vaccines for protection and treatment against naturally occurring diseases and wound infections of military importance, as identified by worldwide medical surveillance and military threat analysis. This project is being coordinated with the Defense Health Program.

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Project 873 conducts research on HIV, which causes acquired immunodeficiency syndrome (AIDS). Work in this area includes refining improved identification methods to determine genetic diversity of the virus, preclinical work in laboratory animals including non-human primates to identify candidates for future vaccine refinement, and evaluating and preparing overseas sites for future vaccine trials. This project is being coordinated with the Defense Health Program.

Project 874 identifies and evaluates drugs, biologics (products derived from living organisms), medical devices, and diagnostics for resuscitation, life support, and post-evacuation restorative and rehabilitative care, as well as trauma care systems for use by field medics and surgeons. Research focus is on identifying more effective critical care technologies and protocols to treat severe bleeding, traumatic brain injury and other blast related injuries, and treatments for ocular injury and visual system dysfunction, as well as laboratory and animal studies of regenerating skin, muscle, nerves, and bone tissue for the care and treatment of battle-injured casualties. This project is being coordinated with the Defense Health Program.

Project FH2 conducts applied research directed toward the sustainment of a healthy force of Warfighters through the entire deployment life cycle.

Project VB4 conducts applied research in systems biology to provide a highly effective mechanism to integrate iterative biological tests, computer simulations, and animal studies. Such refinement efforts using systems biology could ultimately reduce the time and effort invested in medical product refinement. This project is being coordinated with the Defense Health Program.

Project VJ4 examines over a planned 5-year period the mental and behavioral health of Soldiers to counter suicidal behavior. This work will focus on advancing the understanding of the multiple determinants of suicidal behavior, psychopathology (study of the causes and nature of abnormal behavior), psychological resilience, and role functioning. Work on this project is being performed by the National Institute of Mental Health through extramural cooperative research grants in collaboration with the Department of the Army. This project is being coordinated with 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.

All medical applied research is conducted in compliance with U.S. Food and Drug Administration (FDA) or Environmental Protection Agency (EPA) regulations. The FDA requires thorough testing in animals (referred to as preclinical testing) to ensure safety and, where possible, effectiveness prior to evaluation in controlled human clinical trials (upon transition to 6.3 Advanced Technology Research). This PE focuses on research and refinement of technologies such as product formulation and purification and assay refinement with the aim of identifying candidate solutions. This work often involves preclinical testing in animals. The EPA also requires thorough testing of products, such as sterilants, disinfectants, repellents, and insecticides to ensure the environment is adequately protected before these products are licensed for use.

Program refinement and execution is externally peer-reviewed and fully coordinated with all Services as well as other agencies through the Joint Technology Coordinating Groups of the Armed Services Biome

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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	105.762	107.891	106.338	-	106.338
Current President's Budget	104.190	107.891	93.340	-	93.340
Total Adjustments	-1.572	0.000	-12.998	-	-12.998
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	0.342	-			
• SBIR/STTR Transfer	-1.914	-			
• Adjustments to Budget Years	-	-	-12.998	-	-12.998

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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
869: *Warfighter Health Prot & Perf Stnds*	-	37.910	38.907	34.728	-	34.728	33.230	30.317	30.656	31.482	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 conducts research to prevent and protect Soldiers from training and operational injuries, refine mechanisms for detection of physiological and psychological health problems, evaluate hazards to head, neck, spine, eyes, and ears, set the standards for rapid return-to-duty, and determine new methods to sustain and enhance performance across the operational spectrum. This research provides medical information important to the design and operational use of military systems, and this work forms the basis for behavioral, training, pharmacological (drug actions), and nutritional interventions.

The four main areas of study are:
(1) Environmental Health and Protection
(2) Physiological Health
(3) Injury Prevention and Reduction
(4) Psychological Health and Resilience

Promising efforts identified in this project are further matured under PE 0603002A, project MM3.

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 WRAIR, Silver Spring, MD; USARIEM, Natick, MA; U.S. Institute of Surgical Research (USAISR), Fort Sam Houston, TX; and 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: Environmental Health and Protection - Physiological Awareness Tools and Warrior Sustainment in Extreme Environments	3.496	2.038	1.930
Description: This effort evaluates remote monitoring of Soldier physiological status and mitigating/eliminating the effects of heat, cold, altitude, and other environmental stressors on Soldier performance. This effort supports Technology-Enabled Capability			

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT 869: *Warfighter Health Prot & Perf Stnds*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
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 FY 2013-2014. ***FY 2012 Accomplishments:*** Developed altitude acclimatization and work performance models for altitudes between 7,000 and 14,000 feet. Acquired data that will aid in the development of a model of Military performance to reflect the effects of heat stress and hydration. ***FY 2013 Plans:*** Conduct laboratory studies to determine effects of hypoxia (oxygen depletion) on peripheral blood flow during cold exposure. These results will lead to the refinement of preventive measures for Warfighters deployed in high-altitude environments and may be included as components in the altitude and work performance models. ***FY 2014 Plans:*** Will conduct studies to determine whether physiological fatigue in cold environments increases susceptibility to non-freezing cold injury and hypothermia and will develop screening procedures to determine those Warriors most at risk for non-freezing cold injury. These studies will determine the impact of hypoxia (oxygen depletion) on peripheral blood flow responses and susceptibility to non-freezing cold injury			
Title: Physiological Health - Nutritional Sustainment and Fatigue Interventions ***Description:*** This effort evaluates methods for managing and controlling the effects of nutrition and fatigue on Soldier operational performance. This effort supports Technology Enabled Capability Demonstration 7.d, Brain In Combat in FY 2013-2014. ***FY 2012 Accomplishments:*** Investigated whether there is any association between disturbances in nutritional health and the prevalence of Warfighter psychological disorders; determined the impact of weight status on risk of musculoskeletal injury and defined the effect of a high protein diet on musculoskeletal health; defined the muscle metabolic responses to energy deficit for development of treatment interventions; demonstrated effectiveness of a non-prescription medication for promoting fat loss in overweight Warriors. ***FY 2013 Plans:*** Determine the capacity of nutrients from plants to alter oxidative stress (condition where potentially damaging substances exist in cells in excess of the cell's ability to detoxify them), reduced oxygen supply, or chemical-induced toxicity. These results lead to interventions designed to protect Warfighters from environmental hazards; define the effects of metabolic energy availability on cognitive performance; determine whether nutritional interventions can facilitate bone remodeling in response to military training; incorporate a mathematical model of caffeine effects during chronic sleep restriction into the sleep performance model; and refine a cognitive (mental processing) model to predict differential rates of recovery following various chronic sleep restriction operational scenarios. These results increase predictive capability against the effects of fatigue; determine the effects of physiological (human	3.597	6.086	6.103

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
mechanical, physical and biochemical functions) factors, such as genetic makeup, sleep history, and personality on individual differences in physiological resiliency. ***FY 2014 Plans:*** Will establish the nutritional requirements for optimizing Soldier re-fueling; will establish Military Dining Facility serving practices that promote healthy food choices; will establish the nutritional requirements for optimizing bone health; and will develop dietary support interventions that accelerate cognitive recovery after operational stress. These interventions will optimize Soldier recovery from demanding missions through nutrition; will develop mathematical models and algorithms for prediction of cognitive resilience based on physiological factors determined from laboratory studies, which will allow resilience training to be personally optimized; will compare the effectiveness and post-awakening performance profile of novel sleep-inducers against that of currently available pharmaceuticals, which will determine the most efficient intervention for sleep induction; will develop a mathematical method for estimating thermal-work strain from non-invasive measures such as heart rate, skin temperature, heat flux, without the use of thermometer pills, which will allow for the optimization of Soldier load distribution and energy expenditure.			
Title: Injury Prevention and Reduction - Neurosensory Injury Prevention ***Description:*** The Warrior Injury Assessment Manikin analyzes and models the effects of mechanical and operational stressors on Soldier performance, to include acoustic and impact trauma, vision, vibration, and jolt to model the effects of these stressors on the brain, spine, eyes, and hearing. This effort supports Technology-Enabled Capability Demonstration 1.c, Force Protection-Occupant Centric Platform in FY2013-2014. ***FY 2012 Accomplishments:*** Determined thresholds of operationally relevant blunt head injury; completed additional eye injury dose-response modeling for the instrumented headform system; assessed effectiveness of existing hearing protection in continuous high-noise training environments using otoacoustic emissions (sound generated within the inner ear, which can be used as a measure of inner ear health); developed biomedically based injury mechanism criteria to define auditory risk potential; and examined both biophysical and animal models of blast to characterize the nature and extent of effects on the eye. ***FY 2013 Plans:*** Refine standard methodology for the evaluation of vision and ocular sensitivity during rapid transitions between light and dark operational conditions; refine methodology to evaluate blunt facial protection strategies; refine a model that assess the effectiveness of existing and newly developed hearing protection/enhancement strategies during continuous and impulse noise combat operations that predicts the effects of hearing loss in an operational environment; determine additive effects of laser pulses to enable the safe use of military laser systems and provides biomedical data to assess eye protection devices; and assess	7.033	8.824	8.184

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
military ocular (eye) trauma from blast or lasers and outcomes that leads to the prevention and effective mitigation of battlefield eye injuries. ***FY 2014 Plans:*** Will develop improved eye protection standards and ophthalmic (pertaining to the eye) guidelines for protective eyewear that serves the various Warrior occupations and will develop hearing protection strategies for optimized active noise-reduction protection.			
Title: Injury Prevention and Reduction - Musculoskeletal Injury Prevention ***Description:*** This effort evaluates and assesses the effects of repetitive motion during military operations and training on the human body; allows for the prediction of injuries as a result of continuous operations and muscle fatigue; evaluates current standards for return-to-duty; and establishes improved medical assessment methods with the goal of rapid return to duty of Soldiers following injury. 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:*** Developed and validated a model that identified relationships among multi-sensory and musculoskeletal injuries; developed and implemented an injury risk methodology for remediation and prevention in an effort to mitigate lost duty-time due to musculoskeletal injury; and developed strategies to evaluate predictions and generalizations of musculoskeletal injuries. ***FY 2013 Plans:*** Refine a mounted Soldier injury performance assessment battery and assess the physical performance requirements and determine minimal acceptable standards for muscle/skeletal injury for the dismounted Soldier. These results provide data for an improved injury risk analysis capability for the Soldier. ***FY 2014 Plans:*** Will develop a quantitative computational model that can predict physical performance and risk of injury of individual Soldiers and will develop training strategies and/or dietary interventions to improve recovery following intense physical exercise.	5.108	6.937	5.159
Title: Injury Prevention and Reduction - Injury Return to Duty Standards: ***Description:*** This effort evaluates current methods for rapid return-to-duty standards and establishes improved medical assessment methods with the goal of more rapid return to duty of Soldiers following injury. ***FY 2012 Accomplishments:***	2.546	3.752	2.676

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Developed strategies to validate whether hearing following blast or blunt trauma is a predictor of mild Traumatic Brain Injury (mTBI) and evaluated the human vestibular system (system that contributed to sense of balance and spatial orientation) as a predictor of mTBI from blast and blunt trauma. ***FY 2013 Plans:*** Evaluate impulse noise measurement techniques to assess the potential for acoustic (hearing) injury to Soldiers. These results provide an increased predictive capability for acoustic trauma. Determine the effect of a low-level repeated-blast exposure environment on vestibular function (balance and movement). These results lead to the refinement of medical guidelines that prevents impaired Soldiers from being prematurely returned to duty. ***FY 2014 Plans:*** Will compare treatment modalities for impact on return to duty and develop a toolkit for assessment that includes testing vision, hearing, and vestibular (sensory system supporting movement and sense of balance) function; will develop models that predict and prevent auditory (process of hearing) injury; and will develop criteria to improve hearing conservation and guide development of hearing protection equipment for Warriors.			
Title: Psychological Health - Psychological Resilience ***Description:*** This effort refines, validates, and disseminates early interventions to prevent and reduce combat-related behavioral health problems, including symptoms of post-traumatic stress disorder (PTSD), depression, anger problems, anxiety, substance abuse, post-concussive symptoms, and other health risk behaviors and also assesses and refines interventions to enhance and sustain resilience throughout the Warfighter's career. This effort supports Technology Enabled Capability Demonstration 7.d. Brain In Combat in FY2013-2014. ***FY 2012 Accomplishments:*** Established key targeted skills that leaders employed to effectively build resilience and handle behavioral health issues in their units; developed training content for these leader skills; conducted studies to assess effectiveness of new advanced resilience training modules post-deployment and delivered validated training; validated enhanced resilience training techniques and assessed optimal training delivery strategies; assessed post-deployment reintegration strategies; developed and assessed effectiveness of spouse resilience training to enhance mental health and reintegration; and provided evidence-based guidance for adequate resourcing of mental health services for military families. ***FY 2013 Plans:*** Finalize assessment of post-deployment reintegration strategies; conduct studies to show the effectiveness of behavioral health and resiliency skills for leaders; and conduct studies to evaluate the effectiveness of behavioral health and resiliency skills for	10.629	6.566	8.436

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
leaders. These results are used to refine preventive and treatment interventions to enhance the psychological resilience of the Warfighter. ***FY 2014 Plans:*** Will evaluate and determine optimal interventions for preventing and treating deployment-related PTSD and comorbidities (more than one illness) to include medications, best psychotherapy and medication combinations, and alternative therapy protocols, including internet- based cognitive (mental processes) therapy. These intervention strategies will be used to optimize treatment outcomes and to implement more effective, efficient, and economical treatment regimens; will benchmark emerging behavioral health trends through rapid fielding assessment teams to inform resilience training modifications; This effort will ensure rapid response to Warfighter needs and will determine evidence-based recommendations for Soldier reintegration strategies into their units and society; will develop and refine evidence-based resilience training strategies for the deployment cycle; will develop best practice recommendations based on research findings to facilitate Warfighters receiving the best possible training and provider care; and will assess factors that contribute to return-to-duty decisions and conduct research to develop criteria and tools to inform return to duty decisions following psychological injury; This effort will work toward facilitating confidence in the Warfighter and provider that the Warfighter is psychologically fit to return to duty.			
Title: Psychological Health & Resilience - Suicide Prevention and Treatment of PTSD ***Description:*** This effort supports investigation of methods to treat PTSD in a military population and identifies causative and preventive factors in military suicides. ***FY 2012 Accomplishments:*** Conducted assessments to identify long-term effects of deployment (multiple and prolonged deployments, dwell time, and combat intensity) related to mental health symptoms (PTSD, etc.) and other illnesses (respiratory, hearing, functional, and cognitive) and assessed effectiveness of increasing suicide awareness training with decreasing suicide-related behaviors and intentions. ***FY 2013 Plans:*** Refine specific interventions for the most effective means of treating deployment-related PTSD, including medications, psychotherapy, and complementary alternative medicine approaches and refine valid screening and assessment measures for the Soldier at risk of suicide. These early intervention strategies will be used to reduce suicide rates among Service members. Determine effectiveness of suicide prevention training for increasing suicide awareness and decreasing suicide-related behaviors and intent. These results will help increase psychological resilience and mitigate the potential for suicide. Additionally, these results complement work in 6.3 Project MM3 and related DHP programs. ***FY 2014 Plans:*** Will test the effectiveness of a brief, telephone-based intervention to increase behavioral health treatment-seeking among Service members at high risk of suicide; will learn about the type and range of decisions made by behavioral healthcare providers,	3.839	3.270	1.014

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
chaplains, and leaders to address suicide-related events that occur during deployment, the process for making these decisions, and the lessons learned; will assess how suicide-related events were managed and what could be improved; and will develop guidelines and decision aids for use in deployed settings when suicide-related events occur.			
Title: Psychological Health & Resilience - Concussion/Mild Traumatic Brain Injury (mTBI) Interventions ***Description:*** This effort refines and evaluates methods to detect and treat concussion as well as identify and evaluate the effects of cognitive deficits in Soldiers during operations. This effort supports Technology-Enabled Capability Demonstration 7.d, Brain In Combat in FY2013-2014. ***FY 2012 Accomplishments:*** Determined whether concussion/mTBI-related neurocognitive performance deficits predict other objective neurophysiological indicators of functional capability and assessed impact of neurocognitive measures for tracking/monitoring recovery rate and for providing guidance for the determination of return-to-duty status. ***FY 2013 Plans:*** Refine an evidence (data)-based comparative analysis of the foremost neurocognitive (functions of the brain) tests for assessment of mTBI in Soldiers; conduct an assessment to determine which post-concussion syndrome symptoms are caused by sleep disturbance; and refine guidance on drug interventions to improve psychological and neurophysiological functioning post-concussion. These results lead to the refinement of more effective interventions following concussive injury. ***FY 2014 Plans:*** Will conduct research to evaluate the utility of magnetoencephalography (MEG), a cutting-edge imaging technique for the brain, as a tool for differentiating PTSD from the brain injury following a post-concussion event; will compare two imaging techniques (MEG and functional magnetic resonance imaging) for effectively assessing brain injury following a post-concussion event; These efforts will lead to more effective assessment of Warriors brain injury post-concussion and will facilitate appropriate care.	1.662	1.434	1.226
Accomplishments/Planned Programs Subtotals	37.910	38.907	34.728

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

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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
870: *Dod Med Def Ag Inf Dis*	-	16.842	18.987	19.072	-	19.072	20.828	22.500	23.725	25.618	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 conducts applied research for medical countermeasures to naturally occurring infectious diseases that pose a significant threat to the operational effectiveness of forces deployed outside the United States. Effective preventive countermeasures (protective/therapeutic drugs and vaccines and insect repellents and traps) protect the Force from disease and sustain operations by avoiding the need for evacuations from the theater of operations. Diseases of military importance are malaria, bacterial diarrhea, and viral diseases (e.g., dengue fever and hantavirus). In addition to countermeasures, this project funds refinement of improved diagnostic tools to facilitate early identification of infectious disease threats in an operational environment, informing Commanders of the need to institute preventive actions and improve medical care. Major goals are to integrate genomics (DNA-based) and proteomics (protein-based) as well as other new biotechnologies into the refinement of new concepts for new vaccine, drug, and diagnostics candidates.

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) Diagnostics and Disease Transmission Control
(4) Bacterial Disease Threats (diseases caused by bacteria)
(5) Viral Disease Threats (diseases caused by viruses)

For the refinement of drugs and biological products, studies in the laboratory and in animal models provide a proof-of-concept for these candidate products, including safety, toxicity, and effectiveness, and are necessary to provide evidence to the FDA to justify approval for a product to enter into future human subject testing. Additional non-clinical studies are often needed in applied research even after candidate products enter into human testing during advanced technology development, usually at the direction of the FDA, to assess potential safety issues. Drug and vaccine refinement bears high technical risk. Of those candidates identified as promising in initial screens, the vast majority are eliminated after additional safety, toxicity, and/or effectiveness testing. Similarly, vaccine candidates have a high failure rate, because animal testing may not be a good predictor of human response, and therefore candidate technologies/products are often eliminated after going into human trials. Because of this high failure rate, a continuing effort to identify other potential candidates to sustain a working pipeline of countermeasures is critical for replacing those products that fail in testing.

Work is managed by the U.S. Army Medical Research and Materiel Command (USAMRMC) in coordination with the 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.

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Promising medical countermeasures identified in this project are further matured under PE 0603002A, project 810.

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 WRAIR, Silver Spring, MD, and its overseas laboratories; USAMRIID, Fort Detrick, MD; and NMRC, Silver Spring, MD, and its overseas laboratories.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Drugs to Prevent/Treat Parasitic Diseases (harmful effects on host by an infecting organism)	3.925	4.337	4.463
Description: This effort conducts assessments and improves candidate drugs coming from the DoD discovery program and from other collaborations for prevention and treatment of malaria to counter the continuing spread of drug resistance to current drugs; conducts assessments in animal models of currently available drugs for use against cutaneous leishmaniasis (a skin-based disease transmitted by sand flies); and selects the most effective and safe candidates for continued refinement and possible clinical testing.			
FY 2012 Accomplishments: Undertook preclinical effectiveness and toxicity evaluations of selected antiparasitic compounds, both in vitro (outside the body) and in vivo (within a living organism), in rat/nonhuman primates and down-selected for advancement to clinical studies in humans.			
FY 2013 Plans: Evaluate selected compounds for anti-parasitic effectiveness in animal models to further down-select for human trials and validate new malaria and leishmania models for predicting drug effectiveness and toxicity for future drug testing.			
FY 2014 Plans: Will test new refined compounds in animal models for drug safety and effectiveness to evaluate anti- malarial and anti-leishmania activities of these compounds.			
Title: Vaccines for Prevention of Malaria	4.634	4.522	4.199
Description: This effort conducts studies to investigate new candidate vaccines for preventing malaria and selects the best candidate(s) for continued refinement. A highly effective vaccine would reduce or eliminate the use of anti-malarial drugs and would minimize the progression and impact of drug resistance to current/future drugs.			
FY 2012 Accomplishments:			

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APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT 870: *Dod Med Def Ag Inf Dis*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Selected candidate antigens (substance that when introduced into the body stimulates the production of an antibody) for further evaluation in preclinical testing and advanced those candidates demonstrating effectiveness in primate testing toward further development. ***FY 2013 Plans:*** Optimize formulations of candidate antigens (substance that when introduced into the body stimulates the production of an antibody) in animal models for further evaluation in human clinical trials. ***FY 2014 Plans:*** Will assess immune responses of candidate antigens (substance that when introduced into the body stimulates the production of an antibody) and adjuvant (agent that enhances the effect of vaccines) formulations to optimize immunogenicity (ability of a particular substance to provoke an immune response) and effectiveness in animal challenge models.			
Title: Diagnostics and Disease Transmission Control: ***Description:*** This effort designs and prototypes new medical diagnostic and surveillance tools for the field, focusing on bedside and field-deployable diagnostic systems and refines interventions that protect Warfighters from biting insects such as sand flies, responsible for transmitting leishmaniasis, and mosquitoes, which transmit a variety of diseases including dengue fever, Japanese encephalitis, and malaria. ***FY 2012 Accomplishments:*** Developed and optimized a multi-drug resistant organism diagnostic tool in collaboration with a commercial partner; transitioned the dengue virus diagnostic test for the Joint Biological Agent Identification System (JBAIDS) platform to Advanced Development following preclinical trials; and determined the next group of pathogens (infectious agents) for which to develop rapid diagnostic tools with commercial partnership. ***FY 2013 Plans:*** Refine diagnostic tools that provide on-the-spot identification of biting insects/tick/mites and their human/animal pathogen (infectious agent) infection status; evaluate new non-pesticidal technologies for insect population control; refine data package to obtain FDA clearance on the dengue JBAIDS assay; and evaluate next-generation diagnostic system platforms. ***FY 2014 Plans:*** Will incorporate the vector (organisms that transmit infections) diagnostics and human diagnostic assays into the next-generation diagnostic system managed by Program Executive Office, Chemical Biologics and will complete the dengue assay for use on testing mosquitoes to see if they carry the pathogen (infectious agent) of interest to Warfighters.	1.709	1.949	2.040
Title: Viral Threats Research	2.989	3.726	3.771

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT 870: *Dod Med Def Ag Inf Dis*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Description: This effort designs and laboratory tests new vaccine candidates against HIV, dengue and other hemorrhagic fever viruses such as hantaviruses (cause of Korean hemorrhagic fever) and other lethal viruses (i.e., Lassa fever and Crimean-Congo hemorrhagic fever), and assesses other non-vaccine technologies to protect against such lethal viral diseases. Efforts also include establishment and maintenance of clinical trial sites worldwide. ***FY 2012 Accomplishments:*** Continued to develop proof-of-concept molecular vaccines for viruses of military importance; conducted effectiveness studies to develop and/or maintain vaccine test site infrastructure; refined and validated assays in animal studies for future testing of dengue fever vaccine trials; and established partnerships with industry for pre-clinical and clinical evaluation of medical countermeasures. ***FY 2013 Plans:*** Refine vaccines for viruses of military importance; conduct effectiveness studies to refine and/or maintain vaccine test site infrastructure; refine and validate assays in animal studies for future testing of dengue fever vaccine trials; establish partnerships with industry for pre-clinical and clinical evaluation of medical countermeasures; investigate the feasibility of combining vaccines against different agents into single-label, multi-agent vaccines; identify and characterize new populations who are at high risk of being infected with HIV for clinical evaluation of potential vaccine candidates at overseas sites; and produce vaccines for various HIV subtypes and complete evaluation in animals. ***FY 2014 Plans:*** Will identify and develop reagents, assays, and animal models to test the immunogenicity (ability of a particular substance to provoke an immune response) and protective effectiveness of candidate vaccines and other medical countermeasures against dengue, hantavirus, and other lethal viruses of military interest.			
Title: Bacterial Threats ***Description:*** This effort conducts studies to refine antibacterial countermeasures, including vaccine candidates, to prevent diarrhea (a common disease in deployed troops caused by E. coli, Campylobacter, and Shigella), meningitis (a threat to trainees, deployed troops, and military families), wound infection, and scrub typhus (a debilitating mite-borne disease that is developing resistance to currently available antibiotics). ***FY 2012 Accomplishments:*** Determined level of protection of alternative E. coli vaccine in animal challenge studies (animal vaccinated and challenged with bacteria causing diarrhea); performed animal and toxicology studies on alternative (Invaplex-AR) Shigella vaccine; Campylobacter vaccine have been delayed until FY14 due to technical and funding issues; and performed animal wound infection studies on	3.585	4.453	4.599

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT 870: *Dod Med Def Ag Inf Dis*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
several candidate products to prevent wound infection and biofilm (thin resistant layer of microorganisms that helps bacteria survive in wounds) formation. ***FY 2013 Plans:*** Scale-up vaccine formulation process and conduct toxicity testing on additional E. coli vaccine candidates to ensure adequate safety and vaccine protection coverage; conduct preclinical animal studies to determine safety and immune response to live-attenuated Shigella bivalent (two types) vaccine; and perform animal wound infection studies on candidate products to prevent wound infection and biofilm (an aggregate of microorganisms in which cells adhere to each other on a surface) formation. ***FY 2014 Plans:*** Will continue to evaluate new vaccine candidates against three diarrheal pathogens (infectious agents) (Shigella, Campylobacter, and E. coli) in animal models and will evaluate safety and toxicity of selected antigens (substance that when introduced into the body stimulates the production of an antibody) in small animals to further down-select best candidates for future human testing.			
Accomplishments/Planned Programs Subtotals	16.842	18.987	19.072

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 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT 873: *HIV Exploratory Rsch*	

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
873: *HIV Exploratory Rsch*	-	9.117	8.986	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 conducts research on HIV, which causes AIDS. Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for future vaccine trials. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals.

This program is jointly managed through an Interagency Agreement between USAMRMC and the National Institute of Allergy and Infectious Diseases of the National Institutes of Health. This project contains no duplication of effort within the Military Departments or other government organizations.

Work is related to and fully coordinated with work funded in PE 0603105A, project H29.

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 WRAIR and NMRC, Silver Spring, MD, and their overseas laboratories. The Henry M. Jackson Foundation (HMJF), located in Rockville, MD provides support for FDA testing and other research under a cooperative agreement.

Efforts in this project support the Soldier Portfolio and the principal area of Military Relevant Infectious Diseases to include HIV.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: HIV Research Program	9.117	8.986	0.000
Description: This effort assesses new HIV vaccine candidates and worldwide vaccine test sites, tracks HIV disease outbreaks, and analyzes the genetic attributes of HIV threat.			
FY 2012 Accomplishments: Characterized and developed new populations at high risk of being infected with HIV for clinical evaluation of potential vaccine candidates at overseas sites; studied the impact of human genetics on HIV vaccine development, disease acquisition, and			

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT 873: *HIV Exploratory Rsch*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
disease progression; manufactured vaccines for various HIV subtypes present worldwide and completed testing in animals; and evaluated and implemented methods of disease prevention through clinical research. ***FY 2013 Plans:*** Identify, refine, and maintain new clinical trial sites in Africa and Asia; manufacture vaccine candidates based on HIV subtypes present in Africa and Asia to perform pre-clinical testing in laboratory animals; and test selected vaccine candidates in non-human, primate models to test safety and effectiveness of vaccine candidates to down-select best candidates for further testing in humans.			
Accomplishments/Planned Programs Subtotals	9.117	8.986	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 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT 874: *Cbt Casualty Care Tech*	

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
874: *Cbt Casualty Care Tech*	-	16.837	19.821	18.271	-	18.271	16.829	17.693	18.788	20.119	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 refines and assesses concepts, techniques, and materiel that improve survivability and ensure better medical treatment outcomes for Warfighters wounded in combat and other military operations. Combat casualty care research addresses control of severe bleeding, revival and stabilization, prognostics and diagnostics for life support systems (predictive indicators and decision aids), treatment of burns, and traumatic brain injury (TBI). Clinical and rehabilitative medicine research addresses tissue repair including transplant technologies, orthopedic injuries, eye injuries, and face trauma.

Research involves extensive collaboration with multiple academic institutions to refine treatments for combat wounds through AFIRM. This project is coordinated with the Military Departments and other government organizations to avoid duplication.

Research conducted in this project focuses on the following five areas:
(1) Damage Control Resuscitation
(2) Combat Trauma Therapies
(3) Combat Critical Care Engineering
(4) Clinical and Rehabilitative Medicine
(5) Traumatic Brain Injury

All drugs, biological products, and medical devices are refined in accordance with FDA regulations, which govern testing in animals to assess safety, toxicity, and effectiveness and subsequent human subject clinical trials.

Promising efforts identified in this project are further matured under PE 0603002A, project 840.

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 on this project is performed by USAISR, the U.S. Army Dental Trauma Research Detachment (USADTRD), 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 Clinical and Rehabilitative Medicine.

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT 874: *Cbt Casualty Care Tech*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Damage Control Resuscitation	5.094	5.003	3.189
Description: This effort develops and refines knowledge products (such as clinical practice guidelines, manuals, protocols, studies, and media), materials, and systems for control of internal bleeding; minimizing the effects of traumatic blood loss; preserving, storing, and transporting blood and blood products; and resuscitation following trauma. ***FY 2012 Accomplishments:*** Initiated studies of blood vessels, platelets (cell fragments that play a role in blood clotting), and coagulation (blood clotting) factor contributions to the body's ability to properly clot blood following trauma, as well as determine whether blood products cause inflammation. ***FY 2013 Plans:*** Continue coagulation (blood clotting) factor and inflammation studies; validate a portable, rapid, point-of-care device to measure clotting ability to guide providers administering resuscitation; transition diagnostic for coagulopathy of trauma (uncontrollable bleeding resulting from injury) to 6.3 and Advanced Development when sufficiently validated; and then seek FDA approval for its use. ***FY 2014 Plans:*** Will continue validation studies of portable, rapid, point-of-care devices that provide care givers information on clotting ability to guide resuscitation and will perform studies of blood product storage technologies suitable for use under battlefield conditions.			
Title: Combat Trauma Therapies	1.615	1.949	0.611
Description: This effort conducts research to enhance the ability to diagnose, stabilize, and accelerate wound healing and repair of damaged tissue for casualties with survivable wounds to the face and head, extremities, and brain. ***FY 2012 Accomplishments:*** Developed local antibiotic delivery that can be used with negative pressure wound therapy; conducted studies of pre- vs. post-deployment dental classification; conducted research in skin, muscle, and bone repair; and moved work related to neuroprotection research to the TBI program and moved regenerative efforts in craniomaxillofacial trauma (soft tissue and skeletal injuries to the face, head and neck) to the Clinical and Rehabilitative Medicine Research Program. ***FY 2013 Plans:*** Study how biofilms (an aggregate of microorganisms in which cells adhere to each other on a surface) reduce wound healing rate and impair wound closure in traumatic craniomaxillofacial wounds and characterize biofilm diagnostics, dispersal agents, and therapies. ***FY 2014 Plans:***			

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 formulate an anti-biofilm wound gel to combat wound infections, prevent chronic infections, and hasten wound healing.			
Title: Combat Critical Care Engineering ***Description:*** This effort refines diagnostic and therapeutic medical devices as well as associated algorithms, software, and data-processing systems for resuscitation, stabilization, life support, and surgical support that can be applied across the pre-hospital, operational field setting, and initial definitive care facilities. ***FY 2012 Accomplishments:*** Developed advanced monitoring technology to rapidly and accurately detect early-onset of blood loss, continuously estimate blood loss volume, and predict patient's risk for cardiovascular collapse. ***FY 2013 Plans:*** Further refine algorithms to track blood loss under conditions of heat, cold, dehydration, varying rates of blood loss, etc., to determine possible causal relationships. ***FY 2014 Plans:*** Will continue work to optimize algorithms to improve fluid resuscitation and prevent hemorrhagic shock and will work to develop decision support algorithms to guide provision of critical care to casualties at the point of injury, during transport, and in field hospital.	0.753	1.525	1.831
Title: Clinical and Rehabilitative Medicine ***Description:*** This effort conducts laboratory and animal studies on regenerating skin, muscle, nerve, bone tissue, and soft tissue (including the genitalia and abdomen) as well as studies regarding ocular and visual system traumatic injury for the care and treatment of battle-injured casualties. ***FY 2012 Accomplishments:*** Continued evaluation of novel drug delivery, diagnostic, and/or tissue repair strategies for eye injury; evaluated candidate strategies for maxillofacial (head, neck, face and jaw) reconstruction, including wound-healing control and tissue engineering/ regeneration techniques to restore facial features; continued development and standardization of animal models for an artificial means for guiding nerve regeneration; continued studies of chronic bone defect and burn repair; continued studies of soft tissue repair strategies; and continued development and testing of experimental stem cell therapies and scaffolds (tissue-engineered grafts) in animal models. ***FY 2013 Plans:*** Refine novel drug delivery, diagnostic, and tissue repair strategies including stem cell therapies utilizing knowledge deliverables from FY2012; further refine animal models to assess soft and hard tissue regeneration technologies; continue studies of burn,	7.613	8.798	10.626

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT 874: *Cbt Casualty Care Tech*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
scar-less wound, soft tissue, and bone repair strategies; expand refinement and testing of stem cell therapies and scaffolds (tissue-engineered grafts) in animal models; and build on promising approaches from FY2012 by continuing 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 down-select novel drug delivery, diagnostic, tissue repair, and treatment strategies including pharmacologic (drugs) and stem cell therapies for eye trauma injury; will incrementally build on past successes to refine and 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) in animal models to assess soft and hard tissue repair and regeneration; and will build on promising approaches from FY2013 by evaluating candidate strategies for burn and 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: Traumatic Brain Injury ***Description:*** This effort supports refinement of drugs and therapeutic strategies to manage brain injury resulting from battlefield trauma, to include mature drug technologies, novel stem cell strategies, and selective brain cooling. This effort supports Technology-Enabled Capability Demonstration 7.d, Brain in Combat in FY2013 and FY2014. ***FY 2012 Accomplishments:*** Realigned neuroprotection research from the Combat Trauma Therapies task area to the TBI task area and continued studies of a single and combination drug therapies of silent seizures, animal studies of stem cell therapy for repair of brain tissue, and optimizing cooling temperature and duration of cooling to improve functional recovery. ***FY 2013 Plans:*** Further investigate selective brain cooling and non-embryonic stem cells derived from human amniotic fluid as non-traditional therapies for TBI. ***FY 2014 Plans:*** Will continue development of selective brain cooling and neural (nervous system) stem cell transplantation as non-traditional therapies for traumatic brain injury and will develop a combat-relevant animal model of repeated mild TBI/concussion.	1.762	2.546	2.014
Accomplishments/Planned Programs Subtotals	16.837	19.821	18.271

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT 874: *Cbt Casualty Care Tech*

C. Other Program Funding Summary ($ in Millions)

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 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT FH2: *Force Health Protection - Applied Research*	

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
FH2: *Force Health Protection - Applied Research*	-	8.888	6.279	6.316	-	6.316	7.436	6.523	7.568	7.686	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 conducts research to support applied research directed toward the sustainment of a healthy force of Warfighters from accession through retirement. This research focuses on enhanced protection of Soldiers against health threats in military operations and training. Stressors that adversely affect individual Soldier health readiness are identified and studied to refine interventions that will protect Soldiers and improve their health and performance in stressful environments. This is follow-on research that extends and applies findings from over a decade of research on Gulf War Illnesses and other chronic multi-symptom illnesses that have suspected nerve and behavioral alterations caused by environmental contaminants and deployment stressors. Key databases include the Millennium Cohort Study and the Total Army Injury and Health Outcomes Database. These databases allow us to evaluate interactions of psychological stress and other deployment and occupational stressors that affect Warfighter health behaviors.

Force Health Protection applied research is conducted in close coordination with the Department of Veterans Affairs. This project contains no duplication with any effort within the Military Departments and includes direct participation by other Services working on Army projects.

Research conducted in this project focuses on the following three areas:
(1) Millennium Cohort Research
(2) Biomarkers of Exposure and Environmental Biomonitoring
(3) Physiological Response and Blast and Blunt Trauma Models of Thoracic (Chest) and Pulmonary (Lung) Injuries

Promising efforts identified in this project are further matured under PE 0603002A, project FH4.

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; the Naval Health Research Center (NHRC), San Diego, CA; and USARIEM, Natick, MA.

Efforts in this project support the Soldier Portfolio and the principal area of Combat Casualty Care.

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT FH2: *Force Health Protection - Applied Research*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Millennium Cohort Research	4.280	4.068	4.520
Description: This effort supports a long-term study of Soldiers that includes psychological, physical, and spiritual impacts of military service throughout their lifetime. The Millennium Cohort and Deployment Health Task area employs a prospective epidemiological (study of health-event patterns in a society) surveillance research design to address mental health and comorbid (multiple) disorders, including neurological and other chronic degenerative disorders, fitness and readiness performance outcomes, and longer-term physical and mental health illnesses and disease over the life cycle of military Servicemen and women. ***FY 2012 Accomplishments:*** Developed policy recommendations and potential intervention strategies for reduction of PTSD, depression, and anxiety symptoms and factors with a goal to reduce overall mental health symptoms. ***FY 2013 Plans:*** Plan and conduct analyses to further identify gender risk differences for PTSD and depression associated with deployment; examine return-to-duty parameters related to multiple health and injury illnesses; and disseminate strategic findings from studies that support policy formation and guide further research to promote the longer term physical and mental health of the force. These results lead to the formulation of strategies designed to mitigate the adverse psychological effects of military deployments. ***FY 2014 Plans:*** Will determine the long-term and ongoing functional, physical, and mental health issues of Service members (including injury and respiratory/environmental exposures) after military experiences including deployments, training, and other exposures of concern and will characterize emerging or high-profile health threats among Service members through longitudinal assessment. These results will inform preventive and intervention strategies to ensure a healthy and fit force and possibly aid providers and leadership in mitigating adverse health outcomes associated with military experiences.			
Title: Biomarkers of Exposure and Environmental Biomonitoring	2.925	0.757	0.719
Description: This effort supports refinement and evaluation of methods to detect environmental contamination and toxic exposure during military operations. ***FY 2012 Accomplishments:*** Provided rapid toxicity identification for industrial and agricultural chemicals in Army field drinking water supplies and completed and submitted prototype toxicity sensors for evaluation based on the EPA's Technology Testing and Evaluation Program. ***FY 2013 Plans:***			

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT FH2: *Force Health Protection - Applied Research*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Conduct assessment of high-priority Army research needs in nanomaterial characterization, exposure assessment, toxicity studies, or risk assessment. This research provides Soldiers with exposure risk health assessment to the potential health hazards associated with nanomaterials in the environment. ***FY 2014 Plans:*** Will apply a risk ranking system to provide a screening-level assessment for hazardous exposures to the identified Army nanomaterials. These studies will identify Army materiel nanomaterials associated with having the highest initial risk rankings of potential exposures to Warriors			
Title: Physiological Response and Blast and Blunt Trauma Models of Thoracic (Chest) and Pulmonary (Lung) Injury ***Description:*** This effort supports modeling and assessment of the combined effects of blast, impact, and ballistic trauma on the chest and lung system. This effort supports Technology-Enabled Capability Demonstration 7.d, Brain In Combat in FY2013-2014. ***FY 2012 Accomplishments:*** Developed software that evaluated the combined physiological effects of toxic gas exposure; assessed software that estimates lung, heart, and rib injury from blunt trauma caused by debris impact (secondary blast injury); and assessed increased functionality and support of end-users for health hazard assessment, survivability assessment, and personal protection evaluation and improvement. ***FY 2013 Plans:*** Refine software that integrates blast, toxic gas, and blunt trauma injury prediction models into a combined application for integrated blast injury and performance assessment. This research provides Commanders with a single assessment tool for myriad health hazards and with an enhanced capability to assess injury-related risk for the Warfighter. ***FY 2014 Plans:*** Will develop musculoskeletal models for predicting individualized physical performance outcomes of military-relevant tasks following blast or blunt impacts. This research will show the physical decrement associated with blast or blunt impact exposure.	1.683	1.454	1.077
Accomplishments/Planned Programs Subtotals	8.888	6.279	6.316

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT FH2: *Force Health Protection - Applied Research*

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 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT VB4: *System Biology And Network Science 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
VB4: *System Biology And Network Science Technology*	-	4.596	4.802	4.839	-	4.839	4.792	4.869	4.957	5.048	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 conducts research in systems biology to provide a highly effective mechanism to understand, compare, and combine iterative biological tests, computer simulations, and animal studies that have the potential to significantly reduce the time and effort invested in medical product refinement.

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 USAMRMC, Fort Detrick, MD.

Efforts in this project support the Soldier Portfolio and the principal area of Systems Biology/Network Sciences.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Systems Biology	4.596	4.802	4.839
Description: This project conducts multidisciplinary applied research in systems biology designed to understand, compare, and combine animal studies, computational simulations, and biologics (products derived from living organisms).			
FY 2012 Accomplishments: Refined experimental systems for assessment and enhancement of computational models for identifying pharmacological interventions for heat stroke-caused multi-organ failure. Developed multidisciplinary approaches to predict health effects from occupational and environmental stressors and the host responses to environmental hazards. Also assessed the pulmonary (lung) effects of inhalational environmental exposures in Southwest Asia.			
FY 2013 Plans: Perform experiments and high-content screening for host responses to environmental hazards and disease states (initially PTSD and trauma coagulopathy [a condition affecting the blood's ability to clot]); refine and begin validating a computational platform and			

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT VB4: *System Biology And Network Science Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
mathematical models for biological responses to toxicity, disease, and injury; and identify candidate biomarkers for adverse host responses. ***FY 2014 Plans:*** Will evaluate high-content data sets from environmental exposures using computational platform to identify activated-toxicity pathways (understanding the physiology of toxicity) and will screen and down-select candidate PTSD and coagulopathy (abnormal blood clotting) biomarkers for further analysis and validation.			
Accomplishments/Planned Programs Subtotals	4.596	4.802	4.839

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 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT VJ4: *Suicide Prevention/Mitigation*	

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
VJ4: *Suicide Prevention/ Mitigation*	-	10.000	10.109	10.114	-	10.114	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 funds research over a planned 5-year period to examine the mental and behavioral health of Soldiers to counter suicidal behavior. This work will focus on advancing understanding of the multiple determinants of suicidal behavior, psychopathology (study of the causes and nature of abnormal behavior), psychological resilience, and role functioning. A significant thrust area will focus on the refinement of better methods for preventing and mitigating suicidal behavior as well as to improve the overall mental health and behavioral function of Army personnel during and after their military service.

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 on this project is performed by The National Institute of Mental Health (NIMH) through extramural cooperative research grants in collaboration with the Department of the Army.

Efforts in this project support the Soldier Portfolio and the principal area of Military Operational Medicine.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Suicide Prevention/Mitigation	10.000	10.109	10.114
Description: This effort conducts research to better understand the apparent increase in suicide deaths and nonfatal attempts among active duty Soldiers, as well as identify improved prevention/intervention methods for individuals at risk for suicide based on data-driven recommendations. The efforts will be used to decrease suicide rates in both military populations as well as in the general public.			
FY 2012 Accomplishments: Continued epidemiological (population-based) studies to further identify determinants of suicidal behavior as well as potential modifiable risk factors; collected data for suicide-death case control study; and conducted research efforts to assist in improved identification of individuals at greatest risk for suicide as well as to validate screening measures and enhance prevention/ intervention methods.			
FY 2013 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: *Research, Development, Test & Evaluation, Army* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602787A: *MEDICAL TECHNOLOGY*	PROJECT VJ4: *Suicide Prevention/Mitigation*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Continue epidemiological (population-based) studies to further identify determinants of suicidal behavior and potential modifiable risk factors; collect data for suicide-death case control study; and conduct research efforts to assist in improved identification of individuals at greatest risk for suicide, validate screening measures, and enhance prevention/intervention methods. ***FY 2014 Plans:*** Will develop data-driven methods for mitigating or preventing suicide behaviors in service members (Active Duty and Reserve Component Soldiers) from a longitudinal study; will determine modifiable risk and protective factors associated with suicide, mental health and psychological resilience; will refine at risk factors for identification of individuals who are at a greater risk for suicide; will refine improved suicide prevention interventions.			
Accomplishments/Planned Programs Subtotals	10.000	10.109	10.114

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.