

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2007

BUDGET ACTIVITY 3 - Advanced technology development	PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY							
COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate
Total Program Element (PE) Cost	293791	299017	53274	54863	53083	53353	54573	55694
800 TELEMEDICINE TESTBED	2931	3818	5425	4118	3994	4080	4170	4261
801 DEF WOMEN'S HEALTH RES	1438	1780						
804 PROSTATE CANCER RSCH	1916							
810 IND BASE ID VACC&DRUG	16844	21003	21368	22206	20703	20632	21131	21518
814 NEUROFIBROMATOSIS	16294	9889						
819 FLD MED PROT/HUM PERF	988	1159	1202	1265	1235	1267	1295	1323
840 COMBAT INJURY MGMT	16555	22259	23280	25190	25142	25324	25882	26451
893 TISSUE REPLACEMENT	4409							
923 PROSTATE DIAGNOSTIC IMAGE	2684	1186						
929 ARTIFICIAL LUNG TECHNOLOGY	1725	989						
932 Minimally Invasive Surgery (CA)	1054							
938 Tissue Engineering	959							
941 Diabetes Research	4120	2274						
945 BREAST CANCER STAMP PROCEEDS	1915							
954 DIGITAL X-RAY	959							
955 ASSISTIVE TECHNOLOGY	2492	2176						
969 ALCOHOLISM RESEARCH	5368	5439						
97A BIOSENSOR RESEARCH	959	1879						
97B BLOOD SAFETY	3449	989						
97D CENTER FOR AGING EYE	1916	1977						
97O LUNG CANCER RESEARCH	6421							
97T NEUROTOXIN EXPOSURE TREATMENT	22045	26208						
97W SEATREAT CANCER TECHNOLOGY		1582						
97X SYNCHROTRON-BASED SCANNING RESEARCH	8146	5736						
FH4 FORCE HEALTH PROTECTION - ADV	1580	1959	1999	2084	2009	2050	2095	2141

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BUDGET ACTIVITY		PE NUMBER AND TITLE						
3 - Advanced technology development		0603002A - MEDICAL ADVANCED TECHNOLOGY						
TECH DEV								
MB1	ADV DIAGNOSTICS & THERAPEUTIC DIG TECH	959	1582					
MB2	BRAIN, BIOLOGY, AND MACHINE	1916	2473					
MB3	CENTER FOR INTEGRATION OF MEDICINE & INNOV TECH	10543	9494					
MB4	CENTER FOR UNTETHERED HEALTHCARE	959	989					
MB9	JOINT US NORWEGIAN TELEMEDICINE	959	1286					
MC4	SECURE TELEMEDICINE TECH PROGRAM	1916	1286					
MC7	NATIONAL TISSUE ENGINEERING CENTER	1677						
MD1	EMERGENCY TELEMED RESPONSE & ADV TECH	1916	3214					
ME9	BEHAVIORAL/COMPARATIVE GENOMICS	959						
MF2	ADVANCED PROTEOMICS (CA)	1438	1335					
MF9	GENOMIC MEDICINE AND GENE THERAPY (CA)	2108	1780					
MG1	GYNECOLOGIC DISEASE PROGRAM (CA)	3258	3560					
MG3	MEDICAL TRAINING TECH ENHANCEMENT INITIATIVE (CA)	1054	1286					
MG5	NATIONAL FUNCTIONAL GENOMICS CENTER (CA)	4791	8901					
MG7	ON-LINE MEDICAL TRAINING (CA)	2013						
MH1	PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (CA)	1630						
MH2	PROJECT COLLABORATION MATERIAL (CA)	959						
MH3	PROTEOMICS CENTER (CA)	2492	1385					

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BUDGET ACTIVITY		PE NUMBER AND TITLE							
3 - Advanced technology development		0603002A - MEDICAL ADVANCED TECHNOLOGY							
MH4	RAPID BIO-PATHOGEN DETECTION TECHNOLOGY (CA)	959	989						
MH6	RUGGED TEXTILE ELECTRONIC GARMENTS (CA)	1054							
MH7	STUDY OF HUMAN OPERATOR PERFORMANCE (CA)	1438							
MH9	ADVANCE OF NON-INVASIVE GLUCOSE MONITORING (CA)	1630	1434						
MI3	ADVANCES IN BREAST CANCER CARE THERAPY (CA)	1630							
MI4	ALLIANCE FOR NANOHEALTH (CA)	2013	1088						
MI5	BEHAVIORAL GENOMICS SLEEP APNEA RESEARCH (CA)	959							
MI8	FULL-FEATURED PATIENT MONITOR WITH DEFIBRILLATOR	959							
MJ1	EXTRA CORPOREAL MEMBRANE OXYGENATION AT TRIPLER		1582						
MJ2	FIBRINOGEN BANDAGES FOR BATTLEFIELD WOUNDS (CA)	2396	1780						
MJ3	FORT DETRICK TECHNOLOGY TRANSFER INITIATIVE (CA)		1483						
MJ4	HANDS FREE ELECTRONIC HEALTH RECORD (CA)	959							
MJ7	LIGHT-BASED SELF TREATMENT FOR PFB (CA)	959							
MK1	MEDICAL M&S THROUGH SYNTHETIC DIGITAL GENES (CA)	959	1088						
MK2	METROPLEX COMPREHENSIVE MEDICAL IMAGING RESEARCH	6710							
MK6	ORPHAN DISEASE DRUG DISCOVERY	1630							

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BUDGET ACTIVITY		PE NUMBER AND TITLE						
3 - Advanced technology development		0603002A - MEDICAL ADVANCED TECHNOLOGY						
PROGRAM (CA)								
MK7	PEDIATRIC BRAIN TUMOR & NEUROLOGICAL DISEASE PRGM	1438	1186					
MK8	PLASMA STERILIZER (CA)	1438						
ML2	SEAmEd ORAL HEALTH PROJECT (CA)	480						
ML3	SOLDIER-MOUNTED EYE-TRACKING & CONTROL SYSTEM (CA)	2396	1632					
ML5	SURGICAL WOUND DISINFECTION & BIO AGENT DECON PROJ	1916	989					
ML6	Tripler Army Medical Ctr eICU Remote Critical Care	959						
ML7	UNIVERSAL MEDICAL AND SURGICAL PRODUCT CATALOG(CA)	2684	2274					
MM1	WEIGHT MEASUREMENTS & STANDARDS FOR MIL PERSONNEL	1677	989					
MM2	MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)	87834	131630					

A. Mission Description and Budget Item Justification: This program element (PE) supports development of advanced medical technologies to sustain a force of healthy, medically protected warfighters. The primary goal is to mature medical knowledge and technology (drugs, vaccines, and devices) to effectively protect and improve the survivability of U.S. Forces across the entire spectrum of military operations. Efforts are focused in three principal medical areas: Militarily Relevant Infectious Diseases, Combat Casualty Care, and Military Operational Medicine. Activities funded in this PE are externally peer reviewed and, to prevent unnecessary duplication, fully coordinated with other Services and Agencies.

During this phase of development, promising medical technologies are refined and validated through extensive testing, which is closely monitored by the U.S. Food and Drug Administration (FDA) as part of their process for approving new medical products for use in humans. The FDA requires medical products undergo extensive testing in animals and/or other models (pre-clinical) before they can be tested in human subjects (clinical). Clinical trials are conducted in three phases (Phase 1, 2, and 3) to prove the safety and effectiveness of a drug, vaccine, or device for the targeted disease or medical condition. Each successive test includes larger numbers of human subjects and requires FDA approval prior to proceeding with the next test. Work conducted in this PE primarily focuses on advanced technology maturation activities required to obtain FDA approval to initiate Phase 2 clinical trials, although some high risk technologies may require additional maturation and FDA approval to initiate Phase 3 clinical trials prior to transition into a formal acquisition program. Activities in the PE may include completion of pre-clinical animal studies, as well as studies involving human volunteers.

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BUDGET ACTIVITY

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Military Relevant Infectious Disease efforts mature and demonstrate medical countermeasures against naturally occurring diseases of military importance as identified by worldwide medical surveillance and military threat analysis. Example countermeasures include: vaccines, prophylactic interventions, diagnostics, therapeutic drugs, and methods for controlling disease-carrying insects. Countermeasures are developed against parasitic diseases (e.g., malaria and leishmania), and bacterial (e.g., diarrheal diseases and scrub typhus) and viral threats (e.g. hantaviruses and dengue).

Combat Casualty Care efforts mature and demonstrate methods and technologies that can improve medical treatment outcomes for battlefield injuries. These technologies include: drugs, fluids, devices, and diagnostics for resuscitation, treatment of injuries, and life support. Example medical devices and products include blood clotting drugs, freeze-dried plasma, neuroprotective drugs (protection against brain impairment), and operator assisted and automated critical care systems to provide life support functions (resuscitation, and oxygen and fluid administration). Products for prevention of combat maxillofacial (face/neck) injuries and dental disease are also tested and validated.

Military Operational Medicine (MOM) efforts mature and demonstrate biomedical solutions that protect Soldiers and enhance their performance in the face of multiple stressors in operational and training environments. Example products include biomedically-validated design criteria for body armor and helmets, injury models, and physiological algorithms, and factors for monitoring the affects of high altitude, extreme temperatures, hydration, fatigue, isolation, and sleep deprivation on Soldier health and performance. MOM research also addresses lessons-learned from research and treatment of deployment-related illnesses to gain a better understanding of the health threats in military deployments.

The PE contains no duplication with any effort within the Military Departments and is related to, and fully coordinated with, work funded in PE 0602787A. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this PE is performed by Walter Reed Army Institute of Research, Silver Spring, MD; US Army Medical Institute of Chemical Defense, Aberdeen Proving Ground, MD; US Army Medical Institute of Infectious Diseases, Fort Detrick, MD; US Army Research Institute of Environmental Medicine, Natick, MA; US Army Institute of Surgical Research, Fort Sam Houston, TX; US Army Aeromedical Research Laboratory, Fort Rucker, AL; the Naval Medical Research Center, Silver Spring, MD and US Army Medical Detachment Brooks, San Antonio, TX.

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<u>B. Program Change Summary</u>	FY 2006	FY 2007	FY 2008	FY 2009
Previous President's Budget (FY 2007)	300784	50757	58521	56804
Current BES/President's Budget (FY 2008/2009)	293791	299017	53274	54863
Total Adjustments	-6993	248260	-5247	-1941
Congressional Program Reductions		-1142		
Congressional Rescissions				
Congressional Increases		251600		
Reprogrammings	-6993	-2198		
SBIR/STTR Transfer				
Adjustments to Budget Years			-5247	-1941

Software limitations preclude listing the One hundred and twenty FY07 congressional adds totaling \$241142 (after adjustments for Congressional Undistributed Reductions) that were added to this PE. To see the list of congressional adds for this PE, please refer to the Conference Report on Defense Appropriations for Fiscal Year 2007, House Report 109-676, pages 248 to 252.

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BUDGET ACTIVITY 3 - Advanced technology development	PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY						PROJECT 800		
COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	
800 TELEMEDICINE TESTBED	2931	3818	5425	4118	3994	4080	4170	4261	

A. Mission Description and Budget Item Justification: This project funds the advancement and validation of prototype advanced concepts and enabling technology pertaining to Force Health Protection. The goal is to improve warfighter health, survivability, and performance while reducing the requirement for deployed medical professionals. Major efforts include collaborative tools for mission planning and rehearsal that enable deployment of optimally tailored medical support for a deployed force; medical modeling and simulation; medical command and control; and forward echelon telemedicine presence. The current focus is to provide increased situational awareness of the operational and health risks of fatigue, exposure to environmental toxins (toxic industrial chemicals/materials), and enabling technologies for reducing these risks. Evaluation of fatigue countermeasures to validate methods used to mitigate the effects of fatigue and sleep loss that adversely affects the Soldier's ability to sustain both health and performance during prolonged military operations. Additionally, environmental monitoring efforts are directed at demonstration and validation of an Environmental Sentinel Biomonitor that can identify the presence of toxic industrial chemicals in water and monitor potable water sources. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this project is performed by the US Army Center for Environmental Health Research (USACEHR), Fort Detrick, MD; and the Walter Reed Army Institute of Research (WRAIR), Silver Springs, MD.

<u>Accomplishments/Planned Program:</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Sleep Research/Environmental Monitoring: In FY06, verified that increasing levels of sleep loss adversely affects cognitive function, ability to perform risk assessment, sound decision-making process, and situational awareness. Demonstrated and validated the effectiveness of stimulants (caffeine) to improve cognitive abilities. The findings demonstrated that tested stimulants enhanced alertness; however, each stimulant restores only certain aspects of cognitive performance. In FY07, integrate mature components into the Environmental Sentinel Biomonitor (ESB) and conduct field tests. Conduct field studies to validate the Fatigue Intervention Recovery Model (FIRM) to predict military performance (i.e. tactical vigilance, situational awareness, marksmanship). In FY08, will conduct clinical studies of the efficacy of non-traditional fatigue countermeasures (drug interventions) for restoring cognitive performance during extended periods of sleep loss (i.e. cognitive enhancers). The cognitive capacities to be tested will include: decision-making, situational awareness, and judgment. In FY09, will conduct phase II clinical studies to validate the efficacy of cognitive enhancers as a fatigue countermeasure in an operational environment. Integrate ESB components and conduct field testing of the composite system.	2931	3710	5425	4118
Small Business Innovative Research/Small Business Technology Transfer Programs		108		
Total	2931	3818	5425	4118

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BUDGET ACTIVITY 3 - Advanced technology development	PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY						PROJECT 810		
COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	
810 IND BASE ID VACC&DRUG	16844	21003	21368	22206	20703	20632	21131	21518	

A. Mission Description and Budget Item Justification: This project matures and demonstrates medical countermeasures to naturally occurring infectious diseases that can adversely affect the Future Force. Infectious diseases are a major threat to U.S. military forces. Program focus is on prevention, diagnosis and treatment of diseases that can seriously hamper military mobilization, deployment, and effectiveness. Infectious diseases that have had a significant impact on Soldier health include malaria and leishmaniasis (classified as parasitic diseases), bacterial diseases that cause diarrhea (e.g., Shigella, enterotoxigenic Escherichia coli (ETEC), and Campylobacter), and viral diseases such as Dengue Fever. Additional disease threats to deployed and mobilizing forces include meningitis, viral encephalitis, and viruses that cause internal bleeding and kidney failure. Promising medical countermeasures identified through applied research conducted under PE 0602787A, project 870 are further matured under this project. Example countermeasures include: vaccines to protect against malaria, diarrhea, dengue, meningitis, and hemorrhagic fever; insect control measures; and diagnostic devices. Advanced techniques and prototype devices for rapid battlefield identification and diagnosis of infectious diseases are tested and refined. Work is conducted in compliance with US Food and Drug Administration (FDA) regulations for medical products that are intended for human use. FDA requirements include producing drug and vaccine pilot and full production lots using Good Manufacturing Practices (GMP) together with non-clinical studies of these products to support New Drug Applications, and demonstrating their safety and effectiveness in humans under FDA Investigational New Drug (IND) rules. Work is managed by the US Army Medical Research and Materiel Command. The Army is Executive Agent for infectious disease research within the DOD and is responsible for programming and funding all research on Joint and Service-specific requirements, thereby precluding duplication of effort within the Military Departments. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this project is performed by the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD, and its overseas laboratories; the US Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, MD; and the Naval Medical Research Center (NMRC), Silver Spring, MD, and its overseas laboratories.

Accomplishments/Planned Program:	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Drugs to Prevent/Treat Parasitic Diseases: Conduct FDA-required nonclinical (lab-based) testing, select promising malaria and leishmaniasis drug candidates for testing in human subjects, and prepare data package required for FDA approval to proceed with testing in humans. Studies have shown that the malaria parasite can become resistant to treatment with existing drugs, which makes it necessary to continually research new and more effective treatments. In FY06, completed two of five planned initial human subject safety trials (Phase 1, 30-40 volunteers in the United States and Kenya) with Artesunate, a candidate drug to treat severe malaria, and started second clinical safety trial of this drug. Selected a candidate antifolate malaria drug being developed with partner for malaria prevention for testing in humans and prepared data package to gain FDA approval for human subject trials. Assessed for potential human testing two existing drugs that show promise in treating leishmaniasis, a parasitic disease that causes skin ulcers. In FY07, complete human testing of Artesunate and prepare data package for FDA New Drug Application; begin testing of the antifolate antimalarial drug in human subjects (20-40 volunteers, 6-12 months trial) to replace Larium, a drug that may have undesirable side effects; and complete assessment of existing leishmaniasis drugs and proceed with preparation for testing in human subjects if warranted. In FY08, will conduct human subject safety trials (30 volunteers, 8 months trial) on two new antimalarial drugs and assess two existing drugs for effectiveness in treating leishmaniasis. In FY09, will continue testing and studies to identify new candidate antimalarial drug prevention and treatment	3688	3287	2711	3140

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810

candidates and down select current drugs under study as new leishmaniasis treatment. Drugs found effective and safe will transition into advanced development based upon test results.

Vaccines for Prevention of Malaria: Conduct FDA-required nonclinical (lab-based) testing of candidate vaccines, prepare data package required for FDA approval to proceed with further testing, and test promising malaria vaccine candidates in human subjects. A malaria vaccine against the severe falciparum form of malaria and the relapsing vivax form could reduce the need for antimalarial drugs and address the continuing problems with parasite drug resistance and compliance issues with taking antimalarial drugs. In FY06, continued four clinical trials (between 20-400 volunteers in each, duration 6-18 months each) to test safety and effectiveness of promising vaccine components that may be used to formulate a more effective malaria vaccine. In FY07, continue ongoing clinical trials and conduct large scale testing of one of the malaria vaccine candidates (400 African volunteers over 18 months); and establish a partnership with industry for manufacturing a multicomponent vaccine for advanced human subject trials and FDA licensing of a malaria vaccine. In FY08, will finalize a multicomponent candidate malaria vaccine for larger scale testing in human subjects if candidate components prove safe and effective in clinical trials, and initiate clinical testing of a new vivax malaria vaccine. In FY09, will continue refinement of the final formulation of the malaria vaccine and continue ongoing clinical trials to demonstrate effectiveness of candidate vaccines. Vaccines found effective and safe will transition into advanced development based upon test results.

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Bacterial Threats Vaccine Program: Conduct FDA-required non-clinical (lab-based) testing of candidate vaccines, select promising candidate vaccines against diarrhea (significant threat during initial deployments), and meningococcal vaccine candidates (a threat during deployment, training and military families) for testing in human subjects, and prepare data package required for FDA approval to proceed with further testing. In FY06, terminated research on a diarrheal vaccine after it failed in human subject trials; completed human subject safety/effectiveness trials of additional candidate vaccines against two forms of dysentery (bacterial invasion of the gut) with analysis pending. Started initial human subject trial (20-40 volunteers, 6-12 months trial) of a new meningitis vaccine to demonstrate enhanced safety. In FY07, continue testing of candidate diarrheal vaccines and manufacture pilot lot of an improved third diarrheal vaccine for a safety trial using human subjects; and complete initial clinical testing of meningitis vaccine started in FY06. In FY08, will continue with ongoing human subject testing of candidate vaccines by conducting extended Phase 1 clinical trials for a dysentery vaccine (100 volunteers, 12 months trial), including a second-generation oral dysentery vaccine if the current candidate fails in testing. Initiate Phase 1 clinical trials (20-40 volunteers, 6-12 months trial) of two additional diarrheal vaccines. In FY09, will continue larger scale human subject testing for effectiveness of diarrheal vaccine candidates (200 subjects, 12 months trial) and initiate further human subject testing (20-40 volunteers, 6-12 months trial) of a genetically modified meningitis vaccine.

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Viral Threats Vaccine Program: Select most promising vaccine candidates for testing in human subjects against dengue hemorrhagic fever (an increasing threat world-wide) and hantavirus, (severe viral infection that causes internal bleeding). Conduct FDA-required nonclinical testing (lab-based) and disease models of candidate vaccines, and conduct clinical testing of vaccines. In FY06, resumed testing of a DNA-based dengue virus vaccine in human subjects after completing an investigation into an adverse reaction experienced by a participant in the test; completed testing of a second generation dengue virus vaccine in animals as potential lead if current vaccine candidate fails during testing; initiated human subject safety testing (20 volunteers) of one type of hantavirus (Hantaan) vaccine. Conducted final FDA required nonclinical testing of a second strain of Hantavirus vaccine (Puumala) for a combined, broadly protective vaccine against hantaviral hemorrhagic fever strains (HFRS). In FY07, continue testing of the dengue DNA vaccine, manufacture pilot lot of a second-generation dengue vaccine and initiate human safety trial (40 volunteers), complete animal testing and studies with second hantavirus vaccine against a second major HFRS subtype (Puumala virus), manufacture clinical lot of broad spectrum HFRS vaccine (a combined Puumala/Hantaan virus vaccine) for testing in human subjects. In FY08, will continue ongoing human subject testing of multiple hemorrhagic virus vaccines including testing of broad spectrum Hantavirus (HFRS) (200 subjects, 18 months trial) and dengue

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vaccines (40 subjects, 6 months trial). In FY09, will continue with long-term human subject testing of hemorrhagic virus vaccines if study results support their continuation, and down select to most effective and safe dengue vaccine candidates based on larger scale studies that include both adults and children (100-300 volunteers in each group).				
Insect Vector Control and Infectious Disease Diagnostics Programs: Conduct field and human subject testing of field medical diagnostic devices and insect control measures. In FY06, assessed Leishmania DNA-based diagnostic systems in human subject testing, matured, and demonstrated sand fly vector control components such as light traps for collecting insects and identification aides, and demonstrated the effectiveness of tools developed for use by deployed Preventive Medicine Units (PMUs) for detecting relevant diseases such as leishmania and sand fly fever virus in insects. In FY07, conduct additional field and clinical testing of medical diagnostic devices and insect control measures including comprehensive field testing of sand fly control measures, conduct FDA required testing of medical diagnostic systems reaching maturity with focus on commercializing systems, and complete initial human subject testing of Leishmania diagnostic systems or transfer to commercial partner. In FY08, will continue to conduct field testing or clinical testing of medical diagnostic devices and insect control measures with potential completion of several components of the sand fly control tools for PMUs; will conduct human subject trials to complete development of an FDA-approved, field-deployable point-of-care (for use in the clinical) diagnostic device for cutaneous leishmaniasis (a skin ulcer caused by the parasite), and FDA-approved diagnostic tests for latent infection (infection without clinical disease) with Leishmania parasites. In FY09, will transition selected components of sand fly control tools e.g., light traps, screening assays and bednets; will continue to conduct field testing and clinical testing of medical infectious disease diagnostic devices, will transition a clinical diagnostic test for Leishmania infection, and continue to refine and test diagnostic devices and other insect vector control items to attain FDA-approval.	810	2000	2351	2377
Small Business Innovative Research/Small Business Technology Transfer Programs		488		
Total	16844	21003	21368	22206

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COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate
819 FLD MED PROT/HUM PERF	988	1159	1202	1265	1235	1267	1295	1323

A. Mission Description and Budget Item Justification: This project funds 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 a myriad of environmental, physiological stressors, and materiel hazards encountered in training and operational environments. This effort focuses on identifying stressors, and validating methods for assessing risk to the Soldier due to both physical and operational stressors. Research matures and demonstrates methodologies and tools associated with biomechanical-based health risks, injury assessment/prediction, Soldier survivability and performance during continuous operations. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this project is performed by the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD.

<u>Accomplishments/Planned Program:</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Physical Performance Enhancement: In FY06, validated the effectiveness of resistance training in enhancing performance and reducing overall training injuries. Implementation of these findings reduces the incidence of training injuries and thereby enhances Soldier readiness. In FY07, validate the effectiveness of measuring bone and muscle metabolism as a non-invasive injury prediction tool for monitoring the course of musculoskeletal adaptation to strenuous training. In FY08, will validate a method to evaluate pre and post deployment physical status (i.e., body composition, performance, and muscle strength). In FY09, will validate an integrated longitudinal model for predicting individual Soldier and unit musculoskeletal injury and adverse physical performance outcomes.	988	1127	1202	1265
Small Business Innovative Research/Small Business Technology Transfer Programs		32		
Total	988	1159	1202	1265

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COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	
840 COMBAT INJURY MGMT	16555	22259	23280	25190	25142	25324	25882	26451	

A. Mission Description and Budget Item Justification: This project matures, demonstrates, and validates new medical technologies and methods to improve survivability and assure better medical treatment outcomes for warfighters wounded in combat and military operations other than war. Major efforts include hemorrhage control (novel bandages and techniques), resuscitation (fluid replacement and oxygen delivery), prognostics and diagnostics (predictive indicators, decision aids, and devices for triage), and life support (computerized monitors and autonomous patient care devices). Additionally, efforts include combat trauma therapies (novel treatments to minimize tissue damage and accelerate restoration of function) and development of realistic trauma simulators for training of medical personnel. Included are new candidate intravenous clotting drugs; advanced technologies for regrowth of tissue and repair of extremity injuries; freeze-dried plasma to treat hemorrhage; neuroprotective drugs to minimize consequences of head injury; preventive dental care technologies to fight dental disease; and other capabilities to guide and assist the combat medic in the care of wounded on the battlefield and during evacuation. All research is conducted in compliance with US Food and Drug Administration (FDA) requirements. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this project is performed by the US Army Institute of Surgical Research (USAISR), Fort Sam Houston, TX; the US Army Research Institute of Environmental Medicine (USARIEM), Natick, MA; and the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD.

<u>Accomplishments/Planned Program:</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Hemorrhage Control, Blood, and Resuscitative Fluids: Includes work required to validate safety and effectiveness of drugs and medical procedures to prevent or minimize secondary organ failure (including brain and spinal cord injury) after major trauma. In FY06, completed animal studies and sample analyses for blood-clotting products; tested FDA-approved complement inhibitors (CI), i.e. fluids used to reduce tissue and organ injury in animal models to confirm their safety. Two of the CI products improved survival during excessive blood loss. In FY07, determine limitations of activated Factor VII (injectable clotting factor) and freeze-dried plasma to control internal bleeding through animal testing; verify safety and effectiveness of freeze-dried plasma and PDHA, a blood-clotting product derived from blood cells, in human clinical studies; demonstrate the benefit of complement inhibition (reduction of swelling and organ failure) in a large animal model; conduct multiple animal studies using various blood components to compare to the effectiveness of whole blood as a resuscitation fluid; and validate new regimens for treatment of shock. In FY08, will continue animal studies of combinations of products (freeze-dried plasma, synthetic red blood cells, activated Factor VII, fibrinogen) and treatment strategies to best control all forms of bleeding; continue clinical studies of a blood-clotting product derived blood cells for potential to increase survival; determine best transfusion practices and storage practices for blood products; and begin safety and effectiveness clinical trial of CI in hemorrhage-trauma patients. In FY09, will continue to evaluate combinations of products and treatment strategies to best control all forms of bleeding and publish use guidelines for immediate implementation; finalize human clinical trial data to determine maturity relative to FDA approval for PDHA; and continue human clinical trial of CI therapy in hemorrhage-trauma patients.	7258	13340	13464	9760
Combat Trauma Therapies: Includes work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize the immediate and long-term effects from battlefield injuries. In FY06, completed testing necessary to transition a prototype composite long-bone splint to advanced development; tested effectiveness of combinations of growth factors (chemical or	3715	3235	3932	6736

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2007

BUDGET ACTIVITY	PE NUMBER AND TITLE			PROJECT
3 - Advanced technology development	0603002A - MEDICAL ADVANCED TECHNOLOGY			840
biological agents) that accelerate bone regeneration to select best bone substitute; and initiated clinical validation (human testing) of brain trauma biomarkers. Brain trauma research is coordinated with related efforts under the Military Operational Medicine Research Program in PE 0602787A, project 878. In FY07, begin an expanded human safety and efficacy trial for an experimental neuroprotectant drug (NNZ2566) as a treatment for acute silent seizures resulting from a brain injury and continue evaluation of brain trauma biomarkers. In FY08, will continue clinical development of NNZ2566 and complete clinical validation of brain trauma biomarkers. In FY09, will begin extensive multi-center clinical validation of most promising tissue regeneration treatment regimens, complete expanded human safety and efficacy clinical trials for NNZ2566; integrate validated biomarkers and standard physiological parameters (i.e. blood oxygen, chemistry, and pH) in a prototype device for brain trauma biomarker diagnostics and test it in a human clinical trial.				
Far-Forward Medical Systems: Includes diagnostic and therapeutic medical devices, algorithms, software, and data processing systems for resuscitation, stabilization, life support, and dental care. In FY06, validated a special breathing valve that aids blood flow to the heart, completed software specifications for the Computer Assisted Resuscitation Algorithm (CARA), completed formulation of antimicrobial gum to prevent dental disease, and conducted field evaluation of the Warfighter Physiological Status Monitor (WPSM) in realistic training scenarios. The WPSM efforts are coordinated with related efforts under the Military Operational Medicine Research Program PE 0602787A, project 869 and PE 0603002A, project 800. In FY07, refine usage parameters for a special breathing valve that military medical personnel use at all locations on the battlefield as a non-invasive treatment of shock; complete clinical evaluation of the CARA in operating room situations; begin human Phase I clinical testing of the antimicrobial, antiplaque chewing gum; and complete activities required to transition the first generation WPSM to PEO Soldier. In FY08, will complete clinical testing of the automated ventilation algorithm used during surgical operations and intensive care settings; and continue human studies of the antimicrobial, antiplaque chewing gum. In FY09, will start clinical trial of oxygen, ventilation, and fluid resuscitation algorithms integrated into either the Army's integrated litter or the Navy's Lightweight Trauma Module for casualty transport; will complete clinical trials and data analyses required to transition antimicrobial, antiplaque chewing gum to advanced development; and complete prototype development and data analysis of a diagnostic device that provides the field medic enhanced decision support capability for casualty treatment far forward on the battlefield.	4224	3979	5342	7849
Combat Casualty Bioinformatics and Simulation: Includes testing and validation of a data management system to capture and analyze time series data such as heart and respiration rates, and testing and validation of durable and realistic casualty simulators for initial and reinforcement training of medical care providers. In FY06, conducted testing of the RDECOM Advanced Medic Training Technologies system to assess training effectiveness and interoperability. In FY07, finalize prototype by incorporating results from tests run by RDECOM in medic training classes at the AMEDD Center and School. In FY08, will complete revisions of algorithms intended to enhance recovery of usable physiological data and validate use of high-frequency features of electrophysiological signals (electrical measurements of body function) to predict the need for a Life Saving Intervention (LSI). In FY09, will complete development and test validity of an algorithm that incorporates low-, as well as, high-frequency electrophysiological features to provide an automated decision assist output that identifies the specific physiologic state of a patient and the requirement for a specific LSI.	1358	1081	542	845
Small Business Innovative Research/Small Business Technology Transfer Programs		624		
Total	16555	22259	23280	25190

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2007

BUDGET ACTIVITY 3 - Advanced technology development		PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY					PROJECT FH4		
COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	
FH4 FORCE HEALTH PROTECTION - ADV TECH DEV	1580	1959	1999	2084	2009	2050	2095	2141	

A. Mission Description and Budget Item Justification: This project funds efforts that mature, validate, and support enhanced force health protection of Soldiers against threats in military deployments. Health monitoring tools are matured to rapidly identify deployment stressors that also affect 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 affects caused by changes in brain function. This effort builds on knowledge from a decade of research on Gulf War Illnesses (GWI) and other chronic multi-symptom illnesses that have suspected neurotoxin (toxin that destroys/damages the nerve cells) and neuropsychological (branch of psychology dealing with the nervous system, especially brain function) origins. FHP work is conducted in close coordination with the Department of Veterans Affairs. The program is maturing the development of global health monitoring (e.g., neuropsychological monitoring test methodologies), validating clinical signs and symptoms correlating to medical records, diagnosed diseases, and mortality rates. The key databases supporting this program are the Millennium Cohort Study and the Total Army Injury and Health Outcomes Database (TAIHOD). 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 working on Army projects. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this project is performed by the US Army Research Institute of Environmental Medicine (USARIEM), Natick, MA; and the Naval Health Research Center (NHRC), San Diego, CA.

Accomplishments/Planned Program:	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Health Research: In FY06, expanded enrollment in the Millennium Cohort Study (i.e. a study which created a database designed to evaluate the long-term health effects of military service, especially deployments) to more than 108,000 participants, of which nearly one third have recent deployment experience. Conducted long-term validation and reliability analyses of the Cohort database to determine statistical relevance and magnitude of disease associated with GWI. The analyses verify that the Cohort Study will provide an unprecedented capability to understand the health impact of deployment and other occupational exposures prospectively. Validated a significant and continuing increase in disability discharges due to physical injuries over the past decade and identified disability types for targeted focus. In FY07, conduct major data collection for the Millennium Cohort Study by initiating enrollment of more than 30,000 Service members (Panel 3) to further validate and track important health effects of deployment and other military exposures over time. In FY08, will complete enrollment of Millennium Cohort Panel 3 and conduct analyses on data validity, reliability, as well as mental and functional health outcomes. In FY09, will conduct a systematic validation of prospective data to correlate relationships in chronic health effects and multi-symptomatic illnesses. Drawing from disability database analysis to isolate causes, implement, and track results for the most promising interventions to reduce chronic disabilities.	1580	1904	1999	2084
Small Business Innovative Research/Small Business Technology Transfer Programs		55		
Total	1580	1959	1999	2084