

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2008

BUDGET ACTIVITY 3 - Advanced technology development	PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY						
COST (In Thousands)	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	291716	299676	59043	57249	57518	58748	59887
800 TELEMEDICINE TESTBED	3700	5390	4092	3966	4051	4142	4234
801 DEF WOMEN'S HEALTH RES	1743						
804 PROSTATE CANCER RSCH		2385					
810 IND BASE ID VACC&DRUG	19757	21233	22093	20597	20528	21031	21426
814 NEUROFIBROMATOSIS	9684	7949					
819 FLD MED PROT/HUM PERF	1124	1194	1257	1226	1258	1286	1315
840 COMBAT INJURY MGMT	21074	23127	29530	29465	29646	30208	30785
893 TISSUE REPLACEMENT							
923 PROSTATE DIAGNOSTIC IMAGE	1161						
929 ARTIFICIAL LUNG TECHNOLOGY	968						
932 Minimally Invasive Surgery (CA)							
938 Tissue Engineering		1192					
941 Diabetes Research	2227						
945 BREAST CANCER STAMP PROCEEDS	1288						
954 DIGITAL X-RAY		3180					
955 ASSISTIVE TECHNOLOGY	2130	2385					
969 ALCOHOLISM RESEARCH	5326						
97A BIOSENSOR RESEARCH	1840	1589					
97B BLOOD SAFETY	968	1988					
97D CENTER FOR AGING EYE	1936	1589					
97O LUNG CANCER RESEARCH							
97T NEUROTOXIN EXPOSURE TREATMENT	25662	19873					
97W SEATREAT CANCER TECHNOLOGY	1549						
97X SYNCHROTRON-BASED SCANNING RESEARCH	5617	7949					
FH4 FORCE HEALTH PROTECTION - ADV	1898	1987	2071	1995	2035	2081	2127

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2008

BUDGET ACTIVITY		PE NUMBER AND TITLE					
3 - Advanced technology development		0603002A - MEDICAL ADVANCED TECHNOLOGY					
TECH DEV							
MB1	ADV DIAGNOSTICS & THERAPEUTIC DIG TECH	1549	1589				
MB2	BRAIN, BIOLOGY, AND MACHINE	2422	1988				
MB3	CENTER FOR INTEGRATION OF MEDICINE & INNOV TECH	9296	7949				
MB4	CENTER FOR UNTETHERED HEALTHCARE	968					
MB9	JOINT US NORWEGIAN TELEMEDICINE	1259					
MC4	SECURE TELEMEDICINE TECH PROGRAM	1259					
MC7	NATIONAL TISSUE ENGINEERING CENTER						
MD1	EMERGENCY TELEMED RESPONSE & ADV TECH	3147	1988				
ME9	BEHAVIORAL/COMPARATIVE GENOMICS						
MF2	ADVANCED PROTEOMICS (CA)	1307	1192				
MF9	GENOMIC MEDICINE AND GENE THERAPY (CA)	1743					
MG1	GYNECOLOGIC DISEASE PROGRAM (CA)	3486					
MG3	MEDICAL TRAINING TECH ENHANCEMENT INITIATIVE (CA)	1259					
MG5	NATIONAL FUNCTIONAL GENOMICS CENTER (CA)	8715	8347				
MG7	ON-LINE MEDICAL TRAINING (CA)						
MH1	PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (CA)						
MH2	PROJECT COLLABORATION MATERIAL (CA)						
MH3	PROTEOMICS CENTER (CA)	1356					

0603002A
MEDICAL ADVANCED TECHNOLOGY

Item No. 30 Page 2 of 14
267

Exhibit R-2
Budget Item Justification

030 0603002A MEDICAL ADVANCED TECHNOLOGY

266

030 0603002A MEDICAL ADVANCED TECHNOLOGY

266

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2008

BUDGET ACTIVITY		PE NUMBER AND TITLE						
3 - Advanced technology development		0603002A - MEDICAL ADVANCED TECHNOLOGY						
MH4	RAPID BIO-PATHOGEN DETECTION TECHNOLOGY (CA)	968	3975					
MH6	RUGGED TEXTILE ELECTRONIC GARMENTS (CA)							
MH7	STUDY OF HUMAN OPERATOR PERFORMANCE (CA)							
MH9	ADVANCE OF NON-INVASIVE GLUCOSE MONITORING (CA)	1405	795					
MI3	ADVANCES IN BREAST CANCER CARE THERAPY (CA)							
MI4	ALLIANCE FOR NANOHEALTH (CA)	1066	3975					
MI5	BEHAVIORAL GENOMICS SLEEP APNEA RESEARCH (CA)							
MI8	FULL-FEATURED PATIENT MONITOR WITH DEFIBRILLATOR							
MJ1	EXTRA CORPOREAL MEMBRANE OXYGENATION AT TRIPLER	1549						
MJ2	FIBRINOGEN BANDAGES FOR BATTLEFIELD WOUNDS (CA)	1743						
MJ3	FORT DETRICK TECHNOLOGY TRANSFER INITIATIVE (CA)	1453						
MJ4	HANDS FREE ELECTRONIC HEALTH RECORD (CA)							
MJ7	LIGHT-BASED SELF TREATMENT FOR PFB (CA)							
MK1	MEDICAL M&S THROUGH SYNTHETIC DIGITAL GENES (CA)	1066	1589					
MK2	METROPLEX COMPREHENSIVE MEDICAL IMAGING RESEARCH							
MK6	ORPHAN DISEASE DRUG DISCOVERY							

0603002A
MEDICAL ADVANCED TECHNOLOGY

030 0603002A MEDICAL ADVANCED TECHNOLOGY

Item No. 30 Page 3 of 14
268

266

266

Exhibit R-2
Budget Item Justification

030 0603002A MEDICAL ADVANCED TECHNOLOGY

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2008

BUDGET ACTIVITY		PE NUMBER AND TITLE					
3 - Advanced technology development		0603002A - MEDICAL ADVANCED TECHNOLOGY					
PROGRAM (CA)							
MK7	PEDIATRIC BRAIN TUMOR & NEUROLOGICAL DISEASE PRGM	1161	1589				
MK8	PLASMA STERILIZER (CA)	958					
ML2	SEAmEd ORAL HEALTH PROJECT (CA)						
ML3	SOLDIER-MOUNTED EYE-TRACKING & CONTROL SYSTEM (CA)	1598					
ML5	SURGICAL WOUND DISINFECTION & BIO AGENT DECON PROJ	968	1589				
ML6	Tripler Army Medical Ctr eICU Remote Critical Care						
ML7	UNIVERSAL MEDICAL AND SURGICAL PRODUCT CATALOG(CA)	2227					
MM1	WEIGHT MEASUREMENTS & STANDARDS FOR MIL PERSONNEL	968					
MM2	MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)	127168	160101				

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 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.

0603002A
 MEDICAL ADVANCED TECHNOLOGY
 030 0603002A MEDICAL ADVANCED TECHNOLOGY

Item No. 30 Page 4 of 14
 269

Exhibit R-2
 Budget Item Justification

266

030 0603002A MEDICAL ADVANCED TECHNOLOGY

266

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2008

BUDGET ACTIVITY

PE NUMBER AND TITLE

3 - Advanced technology development

0603002A - MEDICAL ADVANCED TECHNOLOGY

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 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). Additionally, research efforts into treatments for face and neck injuries developed in PE 62787 are 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 effects of high altitude, extreme temperatures, hydration, fatigue, isolation, and sleep deprivation on Soldier health and performance. MOM efforts 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 the United States Army Natick Soldier Research, Development and Engineering Center regarding work in blast research that enables armor design, and improved rations for soldiers. Work funded in this project is fully coordinated with efforts undertaken in PE 0602787A. The cited work is consistent with the Department of Defense Research and Engineering Strategic Plan, the Army Science and Technology Master Plan, the Army Modernization Strategy, and the Army Posture Statement. 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.

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2008

BUDGET ACTIVITY	PE NUMBER AND TITLE		
3 - Advanced technology development	0603002A - MEDICAL ADVANCED TECHNOLOGY		
<u>B. Program Change Summary</u>	FY 2007	FY 2008	FY 2009
Previous President's Budget (FY 2008/2009)	299017	53274	54863
Current BES/President's Budget (FY 2009)	291716	299676	59043
Total Adjustments	-7301	246402	4180
Congressional Program Reductions		-1908	
Congressional Rescissions			
Congressional Increases		248310	
Reprogrammings	1011		
SBIR/STTR Transfer	-8312		
Adjustments to Budget Years			-320

Software limitations preclude listing the One hundred two FY08 congressional adds totaling \$248310 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 2008, House Report 110-434, pages 260 to 263.

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2008

BUDGET ACTIVITY 3 - Advanced technology development	PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY					PROJECT 800	
COST (In Thousands)	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate
800 TELEMEDICINE TESTBED	3700	5390	4092	3966	4051	4142	4234

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 provides 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. Efforts focus on the 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. The cited work is consistent with the Department of Defense Research and Engineering Strategic Plan, the Army Science and Technology Master Plan, the Army Modernization Strategy, and the Army Posture Statement. Work in this project is performed by the U.S. Army Center for Environmental Health Research (USACEHR), Fort Detrick, Maryland, and the Walter Reed Army Institute of Research (WRAIR), Silver Spring, Maryland.

<u>Accomplishments/Planned Program:</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Sleep Research/Environmental Monitoring: In FY07, integrated mature components (the electric cell-substrate impedance sensor and the Abraxis enzyme test kit) into the Environmental Sentinel Biomonitor and conducted field tests. Conducted studies to validate the Fatigue Intervention Recovery Model to predict military performance (i.e., tactical vigilance, situational awareness, and marksmanship). In FY08, conduct clinical studies in the laboratory of the efficacy of nontraditional fatigue countermeasures (drug interventions) for restoring cognitive performance during extended periods of sleep loss (i.e., cognitive enhancers). The cognitive test capacities include: decision making, situational awareness, and judgment. In FY09, will conduct expanded (FDA) safety/initial efficacy study in humans through field studies to validate the efficacy of cognitive enhancers as a fatigue countermeasure in an operational environment. Demonstrate validity of near real-time SPARNET-enabled (Spartan Sensor Network) network to improve situational awareness of soldiers during training) model predictions of hydration requirements and heat strain using physiological and weather data. Will demonstrate value of network-enabled predictive biomedical modeling in training mission planning and real-time mission support.	3700	5239	4092
Small Business Innovative Research/Small Business Technology Transfer Programs		151	
Total	3700	5390	4092

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2008

BUDGET ACTIVITY 3 - Advanced technology development	PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY					PROJECT 810	
COST (In Thousands)	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	19757	21233	22093	20597	20528	21031	21426

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, 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 program element 0602787A, project 870, are further matured under this project. Example countermeasures include vaccines and drugs to protect against malaria, diarrhea, dengue fever, 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 U.S. Food and Drug Administration (FDA) regulations for medical products that are intended for human use. FDA requirements include producing drug and vaccine pilot production lots (between 1,000 and 10,000 doses) using Good Manufacturing Practice together with nonclinical studies of these products to support New Drug Applications and demonstrate their safety and effectiveness in humans under FDA Investigational New Drug rules. Work is managed by the U.S. Army Medical Research and Materiel Command. The Army is the Executive Agent for infectious disease research within the Department of Defense 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 the Department of Defense Research and Engineering Strategic Plan, the Army Science and Technology Master Plan, the Army Modernization Strategy, and the Army Posture Statement. Work in this project is performed by the Walter Reed Army Institute of Research, Silver Spring, Maryland, and its overseas laboratories; the U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland; and the Naval Medical Research Center, Silver Spring, Maryland, and its overseas laboratories.

Accomplishments/Planned Program:	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Drugs to Prevent/Treat Parasitic Diseases: Conduct FDA-required, nonclinical (laboratory-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 FY07, completed human testing of artesunate (a new and more effective malaria treatment drug), prepared data package for an FDA New Drug Application, and received approval for compassionate use (available through Centers for Disease Control and Prevention); and completed assessment of existing leishmaniasis drugs for possible development. In FY08, conduct human subject safety trials (30 volunteers, 8-month trial) of one antimalarial drug and assess two existing drugs for effectiveness in treating leishmaniasis. In FY09, will continue nonclinical and clinical testing between two candidates to down select current drug as potential new leishmaniasis treatment.	3287	3704	3828
Vaccines for Prevention of Malaria: Conduct FDA-required, nonclinical (laboratory-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 FY07,	5194	4925	4428

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2008

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT	
3 - Advanced technology development	0603002A - MEDICAL ADVANCED TECHNOLOGY	810	
continued ongoing safety and effectiveness clinical trials, conducted large-scale testing of one of the malaria vaccine candidates (400 African volunteers over 18 months), and continued to work with industry on a multicomponent vaccine for advanced human subject trials and FDA licensing of a malaria vaccine. In FY08, finalize a multicomponent candidate malaria vaccine for larger scale testing in human subjects if candidate components prove safe and effective in clinical trials. Initiate preclinical testing of a new vivax malaria vaccine. In FY09, will continue refinement of the final formulation of the falciparum malaria vaccine and continue ongoing clinical trials to demonstrate effectiveness of candidate vaccines. Vaccines found effective and safe will transition into advanced development.			
Bacterial Threats Vaccine Program: Conduct FDA-required, nonclinical (laboratory-based) testing of candidate vaccines, select promising candidate vaccines against each of the three bacterial causes of diarrhea (significant threat during initial deployments) and meningococcal vaccine candidates (a threat during deployment, training, and for military families) for testing in human subjects, and prepare data package required for FDA approval to proceed with further testing. In FY07, continued testing of candidate diarrheal vaccines and manufactured pilot lot of an improved third diarrheal vaccine for a safety trial using human subjects. Completed initial clinical testing of meningitis vaccine started in FY06. In FY08, continue with ongoing human subject testing of candidate vaccines by conducting extended clinical trials (100 volunteers, 12-month trial), including a second-generation oral dysentery vaccine if the current candidate fails in testing. Initiate clinical trials (20-40 volunteers, 6-12 month trial) of two additional diarrheal vaccines. In FY09, will continue larger scale human subject testing for effectiveness of diarrheal vaccine candidates (200 subjects, 12-month trial) and will initiate further human subject testing (20-40 volunteers, 6-12 month trial) of a genetically modified meningitis vaccine.	5070	6506	7327
Viral Threats Vaccine Program: Select most promising vaccine candidates for testing in human subjects against dengue hemorrhagic fever (an increasing threat worldwide) and hantavirus (severe viral infection that causes internal bleeding). Conduct FDA-required, nonclinical testing (laboratory-based) and disease models of candidate vaccines and conduct clinical testing of vaccines. In FY07, continued testing of the dengue DNA vaccine, manufactured pilot lots of second-generation dengue vaccines, and initiate human safety trial (40 volunteers), completed animal testing and studies with second hantavirus vaccine against a second major Hemorrhagic Fever with Renal Syndrome (HFRS) subtype (Puumala virus), manufactured clinical lot of broad-spectrum HFRS vaccine (a combined Puumala/Hantaan virus vaccine) for testing in human subjects. In FY08, continue ongoing human subject testing of multiple hemorrhagic virus vaccines including testing of broad-spectrum hantavirus (200 subjects, 18-month trial) and dengue vaccines (70 subjects, 6-month trial). In FY09, will continue with long-term human subject testing of hemorrhagic virus vaccines if study results support their continuation and will down select to most effective and safe dengue vaccine candidates based on larger scale studies (120 volunteers).	3962	3901	4035
Insect Vector Control and Infectious Disease Diagnostics Programs: Conduct field and human subject testing of field medical diagnostic devices and insect control measures. In FY07, conducted additional field and clinical testing of medical diagnostic devices and insect control measures, including comprehensive field testing of sand fly control measures, conducted FDA-required testing of medical diagnostic systems reaching maturity with focus on commercializing systems, and completed initial human subject testing of Leishmania diagnostic systems for transfer to commercial partner. In FY08, continue to conduct clinical testing of medical diagnostic device for dengue, and field testing of insect control measures with potential completion of several components of the sand fly control tools for Preventive Medicine Units, and conduct human subject trials in collaboration with commercial partners to support development of an FDA-approved, field-deployable point-of-care (for clinical use) diagnostic device for cutaneous leishmaniasis (a skin ulcer caused by the parasite) and an FDA-approved diagnostic test for latent infection (without signs of clinical disease) with Leishmania parasites. In FY09, will transition selected components of sand fly control tools, such as 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 will continue to refine and test dengue diagnostic device and insect vector control items in collaboration with commercial partners.	2244	1692	2475
Small Business Innovative Research/Small Business Technology Transfer Programs		505	

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2008

BUDGET ACTIVITY

PE NUMBER AND TITLE

PROJECT

3 - Advanced technology development

0603002A - MEDICAL ADVANCED TECHNOLOGY

810

Total

19757

21233

22093

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2008

BUDGET ACTIVITY 3 - Advanced technology development	PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY					PROJECT 819	
COST (In Thousands)	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	1124	1194	1257	1226	1258	1286	1315

A. Mission Description and Budget Item Justification: This project supports the Medical and Survivability technology areas of the Future Force with laboratory validation studies and field demonstrations of biomedical products designed to protect, sustain, and enhance Soldier performance in the face of 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. Effort mature and demonstrate 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 the Department of Defense Research and Engineering Strategic Plan, the Army Science and Technology Master Plan, the Army Modernization Strategy, and the Army Posture Statement. Work in this project is performed by the Walter Reed Army Institute of Research (WRAIR), Silver Spring, Maryland.

<u>Accomplishments/Planned Program:</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Physical Performance Enhancement: In FY07, validated the effectiveness of measuring bone and muscle metabolism as a noninvasive injury prediction tool for monitoring the course of musculoskeletal adaptation to strenuous training. In FY08, 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.	1124	1160	1257
Small Business Innovative Research/Small Business Technology Transfer Programs		34	
Total	1124	1194	1257

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2008

BUDGET ACTIVITY 3 - Advanced technology development	PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY					PROJECT 840	
COST (In Thousands)	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	21074	23127	29530	29465	29646	30208	30785

A. Mission Description and Budget Item Justification: This project matures, demonstrates, and validates new medical technologies and methods to improve survivability and ensure 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 the wounded on the battlefield and during evacuation. Work is conducted in compliance with U.S. Food and Drug Administration (FDA) requirements. The cited work is consistent with the Department of Defense Research and Engineering Strategic Plan, the Army Science and Technology Master Plan, the Army Modernization Strategy, and the Army Posture Statement. Work in this project is performed by the U.S. Army Institute of Surgical Research, Fort Sam Houston, Texas; the U.S. Army Research Institute of Environmental Medicine, Natick, Massachusetts; and the Walter Reed Army Institute of Research, Silver Spring, Maryland.

<u>Accomplishments/Planned Program:</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 FY07, conducted animal testing, which determined limitations of activated Factor VII (injectable clotting factor) and freeze-dried plasma to control internal bleeding; conducted human clinical studies to verify safety and effectiveness of freeze-dried plasma and platelet-derived hemostatic agent (PDHA) (a blood-clotting product derived from blood cells); demonstrated that complement inhibitors (CI) reduce swelling and organ failure in a large animal model; conducted multiple animal studies using various blood components to compare the effectiveness of whole blood as a resuscitation fluid; and validated new regimens for treatment of shock. In FY08, continue animal studies using combinations of products (freeze-dried plasma, synthetic red blood cells, activated Factor VII, and fibrinogen) and treatment strategies to determine which combinations best control all forms of bleeding; continue PDHA clinical studies to determine potential to increase survival; determine best transfusion and storage practices for blood products; and begin safety and effectiveness clinical trial of CI in trauma patients with severe hemorrhage. In FY09, will continue to evaluate combinations of products and treatment strategies to best control all forms of bleeding and will publish guidelines for implementation of these strategies; analyze PDHA human clinical trial data; and continue safety and effectiveness human clinical trials of CI therapy in trauma patients.	12945	13198	9600
Combat Trauma Therapies: Includes work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from battlefield injuries. In FY07, began an expanded human safety and efficacy study for an experimental neuroprotectant drug (NNZ2566) as a treatment for acute silent seizures resulting from a brain injury and continued evaluation of biomarkers in the brain that may indicate brain trauma. In FY08, conduct expanded (FDA) safety/efficacy/dosing studies of neuroprotectant drugs in humans, complete clinical validation of brain trauma biomarkers, and identify potential, mature tissue	3200	3666	11236

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2008

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT		
3 - Advanced technology development	0603002A - MEDICAL ADVANCED TECHNOLOGY	840		
regeneration methods through the Armed Forces Institute of Regenerative Medicine (AFIRM). In FY09, will conduct initial (FDA) safety studies in humans of second-generation neuroprotectants and a prototype diagnostic device for brain trauma, which integrates validated brain trauma biomarkers and standard physiological parameters (i.e., blood oxygen, chemistry, and pH). (Brain trauma research is coordinated with related efforts under the Military Operational Medicine Research Program in PE 0602787A, Project 878.) Will also begin extensive, multicenter, clinical validation of the most promising tissue regeneration treatment regimens through the AFIRM.				
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 FY07, refined usage parameters for a special breathing valve that military medical personnel use at all locations on the battlefield as a noninvasive treatment of shock, completed clinical evaluation of the computer-assisted resuscitation algorithm in operating room situations; and completed activities required to transition the first-generation warfighter physiological status monitor to Program Executive Office Soldier. In FY08, complete clinical testing of the automated ventilation algorithm for operating room and intensive care settings and begin initial, FDA-approved safety study in humans for an antimicrobial, antiplaque chewing gum. In FY09, will begin an (FDA) safety study in humans 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 will complete prototype development and data analysis of a diagnostic device that will provide the field medic enhanced decision support capability for casualty treatment far forward on the battlefield.	3839	5076	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 FY07, finalized prototype by incorporating results from tests run by the Research, Development, and Engineering Command in medic training classes at the U.S. Army Medical Department Center and School. In FY08, 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 lifesaving intervention (LSI). In FY09, will complete development and test validity of an algorithm that incorporates low- and high-frequency signals to provide an automated decision assist tool that identifies the requirement for a specific LSI.	1090	542	845	
Small Business Innovative Research/Small Business Technology Transfer Programs			645	
Total	21074	23127	29530	

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2008

BUDGET ACTIVITY 3 - Advanced technology development		PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY					PROJECT FH4	
COST (In Thousands)	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	1898	1987	2071	1995	2035	2081	2127	

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 Department of Defense's (DoD's) ability to monitor and protect against adverse changes in health, especially mental health effects 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 origins. Force Health Protection work is conducted in close coordination with the Department of Veterans Affairs. The program is maturing the development of global health monitoring (e.g., development of neuropsychological 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. 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 the Department of Defense Research and Engineering Strategic Plan, the Army Science and Technology Master Plan, the Army Modernization Strategy, and the Army Posture Statement. Work in this project is performed by the U.S. Army Research Institute of Environmental Medicine, Natick, Massachusetts, and the Naval Health Research Center, San Diego, California.

<u>Accomplishments/Planned Program:</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Health Research: In FY07, conducted major data collection for the Millennium Cohort Study (a longitudinal effort designed to monitor and protect Soldiers from chronic multi-symptom illnesses) by initiating enrollment of the third cohort, which consisted of more than 30,000 Service members to further validate and track important health effects of deployment and other military exposures over time. In FY08, complete enrollment for Millennium Cohort Study 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, and implement and track results for the most promising interventions to fight chronic disabilities.	1898	1931	2071
Small Business Innovative Research/Small Business Technology Transfer Programs		56	
Total	1898	1987	2071