

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2005

**BUDGET ACTIVITY**  
**3 - Advanced technology development**

**PE NUMBER AND TITLE**  
**0603002A - MEDICAL ADVANCED TECHNOLOGY**

COST (In Thousands)	FY 2004 Actual	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate
Total Program Element (PE) Cost	217736	299561	45160	50300	59146	56408	57029	57596
800 TELEMEDICINE TESTBED	1912	1786	3343	3887	3995	4098	4189	4282
804 PROSTATE CANCER RSCH	973	958	0	0	0	0	0	0
810 IND BASE ID VACC&DRUG	18712	16624	19253	20865	21862	22201	22401	22576
814 NEUROFIBROMATOSIS	19458	23967	0	0	0	0	0	0
819 FLD MED PROT/HUM PERF	1397	1324	1126	1179	1220	1259	1295	1330
840 COMBAT INJURY MGMT	15479	12362	19502	22255	29921	26660	26911	27131
893 TISSUE REPLACEMENT	4183	0	0	0	0	0	0	0
929 ARTIFICIAL LUNG TECHNOLOGY	973	0	0	0	0	0	0	0
932 MINIMALLY INVASIVE SURGERY (CA)	973	3451	0	0	0	0	0	0
938 TISSUE ENGINEERING	0	958	0	0	0	0	0	0
941 DIABETES RESEARCH	4865	4793	0	0	0	0	0	0
954 DIGITAL X-RAY	973	0	0	0	0	0	0	0
955 ASSISTIVE TECHNOLOGY	1946	0	0	0	0	0	0	0
969 ALCOHOLISM RESEARCH	4378	3595	0	0	0	0	0	0
970 ENZYMATIC WOUND DISINFECTANT	0	9108	0	0	0	0	0	0
97A BIOSENSOR RESEARCH	2919	2492	0	0	0	0	0	0
97B BLOOD SAFETY	3989	4602	0	0	0	0	0	0
97D CENTER FOR AGING EYE	973	1917	0	0	0	0	0	0
97E CENTER FOR PROSTATE DISEASE RESEARCH AT WRAMC	4378	4122	0	0	0	0	0	0
97N LUNG CANCER DETECTION	5060	0	0	0	0	0	0	0
97O LUNG CANCER RESEARCH	9243	0	0	0	0	0	0	0
97T NEUROTOXIN EXPOSURE TREATMENT	25295	24924	0	0	0	0	0	0
97W SEATREAT CANCER TECHNOLOGY	1946	2876	0	0	0	0	0	0
97X SYNCHROTRON-BASED SCANNING RESEARCH	0	9778	0	0	0	0	0	0
97Z TAFENOQUINE ANTIMALARIAL AGENT	0	7191	0	0	0	0	0	0

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FH4	FORCE HEALTH PROTECTION - ADV TECH DEV	0	0	1936	2114	2148	2190	2233	2277
MB1	ADV DIAGNOSTICS & THERAPEUTIC DIG TECH	973	7191	0	0	0	0	0	0
MB2	BRAIN, BIOLOGY, AND MACHINE	2919	2876	0	0	0	0	0	0
MB3	CENTER FOR INTEGRATION OF MEDICINE & INNOV TECH	10945	11505	0	0	0	0	0	0
MB4	CENTER FOR UNTETHERED HEALTHCARE	1459	3835	0	0	0	0	0	0
MB7	HEMOGLOBIN BASED OXYGEN CARRIER	0	1343	0	0	0	0	0	0
MB9	JOINT US NORWEGIAN TELEMEDICINE	2724	1727	0	0	0	0	0	0
MC4	SECURE TELEMEDICINE TECH PROGRAM	0	958	0	0	0	0	0	0
MC7	NATIONAL TISSUE ENGINEERING CENTER	0	2397	0	0	0	0	0	0
MC9	MEDICAL SIMULATION TRAINING INITIATIVE	973	0	0	0	0	0	0	0
MD1	EMERGENCY TELEMED RESPONSE & ADV TECH	2919	1343	0	0	0	0	0	0
ME1	CHILDREN'S HOSPICE PROGRAM	973	0	0	0	0	0	0	0
ME3	INSTITUTE FOR RESEARCH AND EDUCATION	3600	3595	0	0	0	0	0	0
ME4	LASER FUSION ELASTIN	0	4602	0	0	0	0	0	0
ME6	MOBILE INTEGRATED DIAGNOSTIC/DATA ANALYSIS SYSTEM	1168	0	0	0	0	0	0	0
ME7	RURAL TELEMEDICINE DEMONSTRATION PROJECT	1946	0	0	0	0	0	0	0
ME8	STABLE HEMOSTAT	2919	0	0	0	0	0	0	0
ME9	BEHAVIORAL/COMPARATIVE GENOMICS	1946	2492	0	0	0	0	0	0
MF1	3D IMAGING & GENOMIC ANAL - BREAST CANCER MGT (CA)	1655	0	0	0	0	0	0	0
MF2	ADVANCED PROTEOMICS (CA)	1168	0	0	0	0	0	0	0
MF3	BATTLEFIELD RESPIRATOR AND VENTILATOR (BRAV) (CA)	1459	1820	0	0	0	0	0	0

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BUDGET ACTIVITY <b>3 - Advanced technology development</b>		PE NUMBER AND TITLE <b>0603002A - MEDICAL ADVANCED TECHNOLOGY</b>								
MF4	BIO-MEDICAL ENGINEERING CENTER (CA)	1168	0	0	0	0	0	0	0	0
MF5	BIOMEDICAL INFORMATION TRANSFER (BIT) (CA)	973	0	0	0	0	0	0	0	0
MF6	DENDRITIC NANOTECHNOLOGY RESEARCH (CA)	2919	0	0	0	0	0	0	0	0
MF7	ELECTRICAL IMPEDANCE SCANNING DEVICE (CA)	973	0	0	0	0	0	0	0	0
MF8	EMERGING TECHNOLOGIES CENTER (CA)	1459	0	0	0	0	0	0	0	0
MF9	GENOMIC MEDICINE AND GENE THERAPY (CA)	3307	3259	0	0	0	0	0	0	0
MG1	GYNECOLOGIC DISEASE PROGRAM (CA)	4135	4122	0	0	0	0	0	0	0
MG2	INTEGRATED INFORMATION SYSTEM (CA)	973	0	0	0	0	0	0	0	0
MG3	MEDICAL TRAINING TECH ENHANCEMENT INITIATIVE (CA)	973	958	0	0	0	0	0	0	0
MG5	NATIONAL FUNCTIONAL GENOMICS CENTER (CA)	4865	8148	0	0	0	0	0	0	0
MG6	NOVEL SAFE EFFECT VACCINES FOR BIODEFENSE/CANCER	6616	0	0	0	0	0	0	0	0
MG7	ON-LINE MEDICAL TRAINING (CA)	1703	0	0	0	0	0	0	0	0
MG8	OPERATING ROOM OF THE FUTURE (CA)	1946	3835	0	0	0	0	0	0	0
MG9	PENNINGTON BIOMEDICAL CENTER (CA)	1751	2492	0	0	0	0	0	0	0
MH1	PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (CA)	3405	1343	0	0	0	0	0	0	0
MH2	PROJECT COLLABORATION MATERIAL (CA)	973	958	0	0	0	0	0	0	0
MH3	PROTEOMICS CENTER (CA)	3307	4122	0	0	0	0	0	0	0
MH4	RAPID BIO-PATHOGEN DETECTION TECHNOLOGY (CA)	1459	0	0	0	0	0	0	0	0
MH5	REGIONAL ANESTHESIA AND PAIN MGMT INITIATIVE (CA)	1168	5752	0	0	0	0	0	0	0

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MH6	RUGGED TEXTILE ELECTRONIC GARMENTS (CA)	2919	1438	0	0	0	0	0	0
MH7	STUDY OF HUMAN OPERATOR PERFORMANCE (CA)	973	2397	0	0	0	0	0	0
MH8	ACCEL DIAGNOSIS-DIGITAL IMAGING PATTERN RECOG (CA)	0	2685	0	0	0	0	0	0
MH9	ADVANCE OF NON-INVASIVE GLUCOSE MONITORING (CA)	0	958	0	0	0	0	0	0
MI1	CLINICAL ED INSTITUTE/SURGERY INTERACTIVE SYS (CA)	0	958	0	0	0	0	0	0
MI2	AD IMAGE PROCESSING TECH FOR BIOMED INFORMATICS	0	2397	0	0	0	0	0	0
MI3	ADVANCES IN BREAST CANCER CARE THERAPY (CA)	0	1246	0	0	0	0	0	0
MI4	ALLIANCE FOR NANOHEALTH (CA)	0	2685	0	0	0	0	0	0
MI5	BEHAVIORAL GENOMICS SLEEP APNEA RESEARCH (CA)	0	958	0	0	0	0	0	0
MI6	CANCER VACCINE (CA)	0	3259	0	0	0	0	0	0
MI7	COLLABORATIVE IN ADVANCED EMR WITH THE ARMY GUARD	0	2397	0	0	0	0	0	0
MI8	FULL-FEATURED PATIENT MONITOR WITH DEFIBRILLATOR	0	1438	0	0	0	0	0	0
MI9	EMERGENCY EYE CARE PROGRAM (CA)	0	958	0	0	0	0	0	0
MJ1	EXTRA CORPOREAL MEMBRANE OXYGENATION AT TRIPLER	0	5752	0	0	0	0	0	0
MJ2	FIBRINOGEN BANDAGES FOR BATTLEFIELD WOUNDS (CA)	0	3356	0	0	0	0	0	0
MJ3	FORT DETRICK TECHNOLOGY TRANSFER INITIATIVE (CA)	0	958	0	0	0	0	0	0
MJ4	HANDS FREE ELECTRONIC HEALTH RECORD (CA)	0	958	0	0	0	0	0	0
MJ5	IMPROVED LUNG CANCER MGMT-ADV IMAGING TECH (CA)	0	2013	0	0	0	0	0	0

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MJ6	LEISHMANIASIS PREVENTION TREATMENT & DIAGNOSIS	0	7191	0	0	0	0	0	0
MJ7	LIGHT-BASED SELF TREATMENT FOR PFB (CA)	0	1438	0	0	0	0	0	0
MJ8	WRAMC HUMAN BRAIN MAPPING FOR CMBT TRAUMA RSCH	0	1727	0	0	0	0	0	0
MJ9	MEDICAL ENTERPRISE MGMT FOR THE U.S. ARMY (CA)	0	958	0	0	0	0	0	0
MK1	MEDICAL M&S THROUGH SYNTHETIC DIGITAL GENES (CA)	0	1438	0	0	0	0	0	0
MK2	METROPLEX COMPREHENSIVE MEDICAL IMAGING RESEARCH	0	6615	0	0	0	0	0	0
MK3	MILITARY SURGEON TRAINING INITIATIVE (CA)	0	958	0	0	0	0	0	0
MK5	MOBILE I V SYSTEM (CA)	0	2492	0	0	0	0	0	0
MK6	ORPHAN DISEASE DRUG DISCOVERY PROGRAM (CA)	0	1917	0	0	0	0	0	0
MK7	PEDIATRIC BRAIN TUMOR & NEUROLOGICAL DISEASE PRGM	0	1438	0	0	0	0	0	0
MK8	PLASMA STERILIZER (CA)	0	1343	0	0	0	0	0	0
MK9	PROPHET FOR COMBAT CASUALTY CARE (CA)	0	480	0	0	0	0	0	0
ML1	RARE BLOOD PROGRAM (CA)	0	958	0	0	0	0	0	0
ML2	SEAMED ORAL HEALTH PROJECT (CA)	0	1820	0	0	0	0	0	0
ML3	SOLDIER-MOUNTED EYE-TRACKING & CONTROL SYSTEM (CA)	0	1438	0	0	0	0	0	0
ML4	SUPERQR POWDER DEVELOPMENT (CA)	0	958	0	0	0	0	0	0
ML5	SURGICAL WOUND DISINFECTION & BIO AGENT DECON PROJ	0	1343	0	0	0	0	0	0
ML6	TRIPLER ARMY MEDICAL CTR EICU REMOTE CRITICAL CARE	0	3835	0	0	0	0	0	0
ML7	UNIVERSAL MEDICAL AND SURGICAL PRODUCT CATALOG(CA)	0	2397	0	0	0	0	0	0

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ML8	UNIVERSAL VACCINE DEVELOPMENT FOR BIOTERRORISM(CA)	0	958	0	0	0	0	0	0
ML9	VASCULAR GRAFT RESEARCH FOR COMBAT SETTINGS (CA)	0	1727	0	0	0	0	0	0
MM1	WEIGHT MEASUREMENTS & STANDARDS FOR MIL PERSONNEL	0	1820	0	0	0	0	0	0

**A. Mission Description and Budget Item Justification:** This program element (PE) supports focused research for healthy, medically protected soldiers, funds research consistent with the Medical and Survivability technology areas of the Future Force, and assures compliance with Food and Drug Administration regulatory requirements for licensure of drugs, vaccines, and medical devices. The primary goal of this program is to provide maximum soldier survivability and sustainability on the battlefield as well as in military operations other than war.

This program element funds maturation of promising medical technologies identified during the applied research phase in the following areas: Militarily-Relevant Infectious Diseases, Combat Casualty Care, and Military Operational Medicine that includes exposure to hazardous military materiel, medical factors to enhance soldier effectiveness, telemedicine, and force health protection.

**Infectious Diseases:** Focuses research on medical protection against naturally occurring diseases of military importance. Methods are identified and matured for infectious disease prevention and treatment including, conducting FDA required pre-clinical and clinical safety and efficacy trials on candidate vaccines, prophylactic interventions, diagnostics and therapeutic drugs. Methods for controlling disease-carrying insect vectors are refined and tested.

**Combat Casualty Care:** Matures and demonstrates methods for the care of trauma and burns due to battlefield injuries. FDA pre-clinical and clinical safety and efficacy testing is included for candidate drugs, biologics, and diagnostics for resuscitation, treatment of injuries and life support. Candidate medical devices and products for the warfighter include: clotting drugs, freeze dried plasma, neuroprotective drugs, handheld acoustic energy hemorrhage control device, and assisted automated critical care system. Candidate products for prevention of combat maxillofacial (face/neck) injuries and reduction of lost time due to dental disease are refined and demonstrated.

**Military Operational Medicine (MOM):** Research focuses on refining and demonstrating biomedical solutions that protect soldiers and enhance their performance in the face of multiple stressors in operational and training environments. Candidate products such as soft body armor and biomonitors to protect soldiers from injuries resulting from exposure to hazardous environments and materiel are refined and demonstrated. Prevention of health and performance degradation in military environments is another important objective of MOM research. This research examines and refines selected physiological indicators and associated algorithms/sensors that potentially indicate performance degradation produced by operational stressors such as high altitude, extreme temperatures, hydration, fatigue, isolation, and sleep deprivation. Findings from research and treatment of Gulf War Illness are used to better understand military health issues to protect Service members against health threats in military deployments.

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BUDGET ACTIVITY

**3 - Advanced technology development**

PE NUMBER AND TITLE

**0603002A - MEDICAL ADVANCED TECHNOLOGY**

The PE contains no duplication with any 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 PE is performed by the Walter Reed Army Institute of Research, Silver Spring, MD; U.S. Army Medical Institute of Chemical Defense, Aberdeen Proving Ground, MD; U.S. Army Medical Institute of Infectious Diseases, Fort Detrick, MD; U.S. Army Research Institute of Environmental Medicine, Natick, MA; U.S. Army Institute of Surgical Research, Fort Sam Houston, TX; and the U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL; and for infectious disease research, the Naval Medical Research Center, Silver Springs, MD.

<u>B. Program Change Summary</u>	FY 2005	FY 2006	FY 2007
Previous President's Budget (FY 2005)	38404	46905	51529
Current Budget (FY 2006/2007 PB)	299561	45160	50300
Total Adjustments	261157	-1745	-1229
Net of Program/Database Changes			
Congressional Program Reductions	-9340		
Congressional Rescissions			
Congressional Increases	279000		
Reprogrammings			
SBIR/STTR Transfer	-8503		
Adjustments to Budget Years		-1745	-1229

Change Summary Explanation:

Eighty FY05 Congressional adds totaling \$279000 were added to this PE. These one year Congressional adds are listed individually as project lines in this R-2 Exhibit, and the amounts shown correspond to the amounts of the Congressional adds. No additional funds are required to complete these projects.

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2005

**BUDGET ACTIVITY**  
**3 - Advanced technology development**

**PE NUMBER AND TITLE**  
**0603002A - MEDICAL ADVANCED TECHNOLOGY**

**PROJECT**  
**800**

COST (In Thousands)	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
	Actual	Estimate						
800 TELEMEDICINE TESTBED	1912	1786	3343	3887	3995	4098	4189	4282

**A. Mission Description and Budget Item Justification:** This project supports the Medical technology area of the Future Force by developing and demonstrating future medical concepts of operations, operational architectures, and operational requirements to support forward echelon telemedicine presence, medical command and control, and collaborative planning tools for mission planning and rehearsal. Major efforts include sleep research and environmental monitor development. It funds development, evaluation, and demonstration of prototype advanced technology concepts and materiel for provision of enhanced Force Health Protection. 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 U.S. Army Research Institute of Environmental Medicine, Natick, MA.

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BUDGET ACTIVITY  
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PE NUMBER AND TITLE  
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PROJECT  
**800**

**Accomplishments/Planned Program**

Sleep Research/Environmental Monitor - In FY04, determined the amount of recovery sleep needed following sleep restriction. Preliminary results established the number of consecutive nights of 8 hours TIB (time in bed) needed to recover from chronic sleep restriction (defined as nightly sleep restricted to 3 hours TIB across 7 nights).  
 In FY05, conduct comparative studies of higher order mental abilities that reflect militarily relevant capacities (e.g., judgment/decision-making, distinguishing friend from foe, course-of-action determination, and situational awareness) to determine which may be degraded by sleep loss and determine if any can be restored through use of stimulants.  
 In FY06, will develop repeatable measures of the most sensitive measures to allow detection of changes in higher order mental abilities with increasing levels of sleep deprivation (most current measures of higher-order mental abilities are single administration only) and their restoration using stimulants.  
 In FY07, will determine efficacy of caffeine (available over-the-counter, non-proprietary stimulant) in comparison to dextroamphetamine and modafinil (prescription-only, proprietary stimulants) for restoring operationally relevant high-order mental performance versus simple psychomotor performance. Integrate Environmental Sentinel Monitor components and conduct field test.

FY 2004	FY 2005	FY 2006	FY 2007	
1912	1786	3343	3887	
<b>Totals</b>	<b>1912</b>	<b>1786</b>	<b>3343</b>	<b>3887</b>

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**BUDGET ACTIVITY**  
**3 - Advanced technology development**

**PE NUMBER AND TITLE**  
**0603002A - MEDICAL ADVANCED TECHNOLOGY**

**PROJECT**  
**810**

COST (In Thousands)	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
	Actual	Estimate						
810 IND BASE ID VACC&DRUG	18712	16624	19253	20865	21862	22201	22401	22576

**A. Mission Description and Budget Item Justification:** This project matures and demonstrates medical countermeasures to naturally occurring infectious diseases that can affect the Future Force. Infectious diseases pose a significant threat to operational effectiveness and forces deployed outside the United States. Countermeasures will protect the force from infection during sustained operations by preventing hospitalizations and evacuations from the theater of operations. Major efforts include: malaria, diarrheal, dengue, meningitis, and hemorrhagic fever vaccine development; antimalarial drug candidate testing; and insect vector control and infectious disease diagnostic development. Of major importance to the military are the parasitic disease malaria and leishmaniasis, the bacterial diseases responsible for diarrhea (i.e., caused by Shigella, enterotoxigenic Escherichia coli (ETEC), and Campylobacter), and viral diseases (e.g., dengue fever and hantaviruses). Research also develops improved materiel for control of insect/arthropod disease vectors and addresses a variety of infectious disease threats to deployed and mobilizing forces, including meningitis, viral encephalitis, and hemorrhagic fevers (e.g., hemorrhagic fevers with renal syndrome (HFRS)). Improved diagnostic capabilities are also pursued that enable rapid battlefield identification and management of diseases and allow informed medical operational and tactical decisions. Program goals include preclinical and clinical testing of protein and DNA vaccines; testing new technologies to enhance effectiveness and duration of vaccines; compounding and testing multicomponent vaccines to provide protection against multiple disease strains; producing vaccines and antimalarial drugs under U.S. Food and Drug Administration (FDA) regulated Good Manufacturing Practices and demonstrating their safety and efficacy under FDA Investigational New Drug (IND) applications. Work is managed by the U.S. Army Medical Research and Materiel Command. The Army is the lead service for infectious disease research. This project contains no duplication with any 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, Silver Spring, MD and its overseas laboratories; U. S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD; and the Naval Medical Research Center, Silver Spring, MD and its overseas laboratories.

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PROJECT  
**810**

**Accomplishments/Planned Program**

	FY 2004	FY 2005	FY 2006	FY 2007
<p><b>Malaria Vaccines</b> - In FY04, conducted FDA Phase 1 and Phase 2 trials of several candidate malaria vaccine components such as Merozoite Surface Protein-1 and membrane antigen-1 with the goal of defining the vaccine technology and components for broadly protective malaria vaccine.</p> <p>In FY05, test malaria blood stage vaccine components for integration into lead malaria vaccine candidate; and continue clinical testing of promising malaria vaccine components including additional preventive liver stage candidate antigens.</p> <p>In FY06, will continue Phase 1 and Phase 2 clinical testing of several promising malaria vaccine components.</p> <p>In FY07, will conduct Phase 1 human clinical trial with candidate multicomponent vaccines; start Phase 2 clinical trial of multicomponent vaccines; and establish partnership with industry for manufacturing of multicomponent vaccine for advanced clinical trial and future FDA licensure.</p>	4620	5075	5416	5936
<p><b>Diarrheal Vaccines</b> - In FY04, successfully completed initial Phase 1 clinical trials for Shigella (S.) sonnei and dysentrie vaccines. Started Phase 1 clinical studies of Campylobacter vaccines.</p> <p>In FY05, continue clinical testing of lead Campylobacter vaccine; conduct Phase 1 clinical trials of one component of multiagent Shigella vaccine and a new subunit vaccine concept S. flexneri 2a (Invaplex). Conduct a Phase 2 clinical trial of encapsulated ETEC vaccine.</p> <p>In FY06, will complete a Phase 2 clinical trial with Campylobacter vaccine.</p> <p>In FY07, will conduct Phase 2 clinical trial with Invaplex as intranasal vaccine. Will prepare improved ETEC vaccine for Phase 1 clinical trial.</p>	4473	3628	4304	4847
<p><b>Dengue, Meningitis and Hemorrhagic Fever with Renal Syndrome (HFRS) Vaccines</b> - In FY04, completed pre-Phase 1 clinical trial submissions and product manufacture of dengue DNA and HFRS vaccines. Completed preclinical testing and prepared for clinical studies of a monovalent group B meningococcal vaccine.</p> <p>In FY05, begin preclinical testing of new molecularly modified dengue virus and tetravalent DNA vaccine candidates. Conduct Phase 1 and start Phase 2 testing of HFRS vaccine.</p> <p>In FY06, will conduct additional clinical testing of best dengue vaccine candidates. Continue clinical testing of HFRS to demonstrate safety; and begin clinical testing for new group B meningococcal vaccine.</p> <p>In FY07, will start Phase 1 clinical trial of a multivalent (active against several strains of an organism) vaccine group B vaccine; and continue critical Phase 2 testing of HFRS and dengue vaccines.</p>	4342	4251	4084	4638

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<b>Accomplishments/Planned Program (continued)</b>	FY 2004	FY 2005	FY 2006	FY 2007
<p>Antimalarial Drug Candidates - In FY04, completed all FDA-required preclinical toxicity testing of Artesunate and submitted application for Phase 1 clinical testing; moved new candidate drugs for prevention of malaria into preclinical testing and down-selected best candidate for clinical testing.</p> <p>In FY05, complete Phase 1 a, b, and c clinical testing of Artesunate. Continue to test new drugs to prevent malaria and select best candidates for clinical trials.</p> <p>In FY06, will complete most Phase 2 clinical testing of Artesunate, a promising new malaria drug.</p> <p>In FY07, will complete clinical testing of Artesunate and submit New Drug Application to FDA.</p>	2398	3055	3502	3646
<p>Insect Vector Control and Infectious Disease Diagnostics - Insect Vector Control and Infectious Disease Diagnostics - In FY04, defined components and tested Dengue Vector Control System (DVCS) components at multiple field sites; identified critical infectious disease diagnostic components for use in a joint services biological agent identification and diagnostic system; evaluated candidate leishmania diagnostics tests for rapid fielding. Began sand fly vector control testing and evaluation.</p> <p>In FY05, continue component product improvements and assess potential point of care and hospital-based infectious disease diagnostics systems including malaria.</p> <p>In FY06, will transition the DVCS components into the next phase of development and assess leishmania diagnostic system; and will develop approaches to supplement infectious disease diagnostics not compatible with joint diagnostic system. Will continue sand fly vector control component testing and evaluation.</p> <p>In FY07, will initiate comprehensive field-testing of sand fly control measures and transition to the Preventive Medicine Detachment tool kit. Will continue to provide additional diagnostic sets for integration into Joint Biological Agent Identification and Diagnostic System and point of care diagnostic sets for testing.</p>	2879	615	1947	1798
<b>Totals</b>	<b>18712</b>	<b>16624</b>	<b>19253</b>	<b>20865</b>

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2005

BUDGET ACTIVITY <b>3 - Advanced technology development</b>	PE NUMBER AND TITLE <b>0603002A - MEDICAL ADVANCED TECHNOLOGY</b>	PROJECT <b>819</b>						
COST (In Thousands)	FY 2004 Actual	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate
819 FLD MED PROT/HUM PERF	1397	1324	1126	1179	1220	1259	1295	1330

**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 and physiological stressors and materiel hazards in training and operational environments. Major efforts include chemical and bacterial hazard identification and risk assessment methods. This research matures development of tools for assessing weapon system user health risks, diagnostic tools and treatments for laser eye injuries on the battlefield, injury prediction tools for assessing soldier survivability, effective individual protective equipment, assessments concerning drugs to sustain soldier performance during continuous operations, and tools for assessing health risks to soldiers in operational environments. 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, Silver Spring, MD and the U.S. Army Institute of Chemical Defense, Aberdeen, MD.

<b>Accomplishments/Planned Program</b>	FY 2004	FY 2005	FY 2006	FY 2007
Chemical & Bacterial Hazard Research - In FY04, the Environmental Protection Agency validated the nucleic acid-based coliform bacterial detection system that can protect drinking water supplies by detecting the viability (live or dead) of coliform bacteria. In FY05, develop methods using gene micro-array technologies to identify biomarkers that indicate exposure to militarily relevant chemical hazards. In FY06, will conduct test using laboratory animals and select biomarkers that indicate chemical exposure. In FY07, will identify potential human biomarkers through extrapolation of animal data.	1397	1324	1126	1179
<b>Totals</b>	<b>1397</b>	<b>1324</b>	<b>1126</b>	<b>1179</b>

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BUDGET ACTIVITY <b>3 - Advanced technology development</b>	PE NUMBER AND TITLE <b>0603002A - MEDICAL ADVANCED TECHNOLOGY</b>					PROJECT <b>840</b>			
COST (In Thousands)	FY 2004 Actual	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	
840 COMBAT INJURY MGMT	15479	12362	19502	22255	29921	26660	26911	27131	

**A. Mission Description and Budget Item Justification:** This project matures and demonstrates new medical technologies in support of the Future Force. Major efforts include: hemorrhage control, blood and resuscitative fluids discovery and development; combat trauma therapies; far-forward medical systems (including diagnostic and therapeutic medical devices) development; and combat casualty care bioinformatics and simulation development. Included are new candidate intravenous clotting drugs; advanced technologies for treating extremity injuries to bone and flesh; freeze-dried plasma to treat hemorrhage and further reduce the medical footprint; neuroprotective drugs to minimize consequences of head injury; preventive dental care technologies including peptides to fight dental disease; and remote triage technologies designed to maximize field medic resources. The “Warrior Medic,” a promising Future Force medical technology capabilities, will enable the combat medic to rapidly assess casualty vital signs and link to other physiological monitors. Other key technologies funded include: new and advanced resuscitation fluids and strategies for combat medic administration that improve survival of casualties with severe blood loss (shock) on the battlefield; an automated assisted critical care system for enhanced management, transport, and survival of stabilized casualties far-forward, within and outside of the battle area; and a handheld system employing acoustic energy to control internal hemorrhage for forward use at the battalion aid station. Selected technologies are integrated into Medical Mission Packages incrementally to provide comprehensive far-forward treatment for the Future Force. All research is conducted in compliance with 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 U.S. Army Institute of Surgical Research, Fort Sam Houston, TX, U.S. Army Research Institute of Environmental Medicine, Natick, MA, and the Walter Reed Army Institute of Research, Silver Spring, MD.

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February 2005

BUDGET ACTIVITY  
**3 - Advanced technology development**

PE NUMBER AND TITLE  
**0603002A - MEDICAL ADVANCED TECHNOLOGY**

PROJECT  
**840**

**Accomplishments/Planned Program**

Hemorrhage Control, Blood and Resuscitative Fluids - including discovery and development of drugs, biologicals, and medical procedures to prevent or minimize secondary organ system injury and failure (including brain and spinal cord injury) after major trauma. In FY04, studied the effectiveness of candidate hemorrhage control agents (gel, foam, liquid), drugs, and high intensity focused ultrasound in controlling severe internal bleeding; conducted studies of candidate packaging systems for freeze-dried blood products that will enhance delivery and storage of blood products in the field; conducted clinical studies to select the best commercially available resuscitation fluid(s); evaluated the maximum tolerable delay in administration of resuscitation fluids. In FY05, conduct studies in animals of a handheld device that stops bleeding with sound waves for use at the battalion aid station; study in animals the effectiveness of candidate drugs and agents to enhance blood clotting and restore normal blood clotting; conduct clinical studies of freeze-dried plasma; finalize guidelines for the optimum resuscitation strategy; conduct studies of oxygen transport and free radical scavenging fluids; conduct investigation of inhibiting complement activation as a method of reducing tissue damage associated with shock. In FY06, will complete animal studies and sample analyses from coagulation studies; will conclude comparative studies of resuscitation fluids; will test FDA-approved complement inhibitors in small animals to determine their safety; refine model for assessing resuscitation requirements. In FY07, will complete data analyses from coagulation studies; will recommend best new fluid for resuscitation; and will select the most promising complement activation inhibitor and introduce into clinical trials; will complete guidelines for resuscitation and evacuation of head-injured patients.

FY 2004	FY 2005	FY 2006	FY 2007
6116	4509	9439	13090

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BUDGET ACTIVITY  
**3 - Advanced technology development**

PE NUMBER AND TITLE  
**0603002A - MEDICAL ADVANCED TECHNOLOGY**

PROJECT  
**840**

**Accomplishments/Planned Program (continued)**

Combat Trauma Therapies - including discovery of drugs, biologicals, and medical procedures to minimize the immediate and long term effects from battlefield injuries. In FY04, completed Phase 2 clinical trials to replace morphine on the battlefield with a nasally administered Ketamine that does not impair cognitive performance; transitioned advanced tourniquet use guidelines to the Army Medical Department Center and School; transitioned three candidate one-handed tourniquets to advanced development; evaluated a wound-protectant device and an improved tourniquet device in animals; conducted proof-of-concept studies of a small antimicrobial wound-cleaning device; conducted proof-of-concept studies of lightweight materials and splints for fracture stabilization; completed maturation of a new penetrating head injury (PHI) model; identified a lead drug-development candidate for the treatment of acute, early brain seizures arising from traumatic brain injuries. In FY05, commence Phase 3 clinical trial of Ketamine in relevant models and quantify effects as compared to Morphine; conduct Phase 1 clinical tests of an improved tourniquet; mature and demonstrate wound-cleaning devices, antimicrobial bone graft substitutes and lightweight materials for splints; mature prototype of device to assess tissue viability. Conduct neuroprotection drug studies in the PHI model to identify a drug to improve survival and residual brain function in casualties with brain injury; conduct studies to determine if resuscitation requirements are altered after traumatic brain injury. In FY06, will transition long bone splint to advanced development; and select best bone substitute. In FY07, will begin human clinical trials of tissue viability assessment device; will transition best bone substitute material to advanced development; and will use the PHI model in further studies to evaluate the body's response mechanism to this type of injury.

FY 2004	FY 2005	FY 2006	FY 2007
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3689	2509	4023	3051
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February 2005

BUDGET ACTIVITY  
**3 - Advanced technology development**

PE NUMBER AND TITLE  
**0603002A - MEDICAL ADVANCED TECHNOLOGY**

PROJECT  
**840**

**Accomplishments/Planned Program (continued)**

Far-forward Medical Systems - including diagnostic and therapeutic medical devices and associated algorithms, software and data processing systems for resuscitation, stabilization, life-support, surgical support, and dental care. In FY04, adapted micro-impulse radar (MIR) monitor into a wearable prototype for continuous monitoring through soldier clothing; selected a set of sensors that detect ballistic wounding and life signs that are integrated with hydration, and sleep status sensors. In FY05, complete maturation of formulation and application methodology of an anticavity/antiplaque food additive to prevent dental disease; transition handheld MIR vital signs monitor to System Development and Demonstration; complete algorithms for detection of ballistic wounding, life signs, hydration and sleep status in the prototype Future Force Warrior ensemble; complete human trials of a fieldable acoustic collapsed lung detector; demonstrate proof of concept of closed loop oxygen and ventilation delivery system and start on fluid infusion system. In FY06, will complete integration of the sensor suite, and generate algorithms with the Personal Area Network; will complete integration of the initial capability with Future Force Warrior Advanced Technology Demonstration; will evaluate relationships among variables that signal cardiovascular collapse and indicate the need to apply a Life Saving Intervention (LSI); will demonstrate effectiveness of closed loop oxygen and ventilation control and fluid resuscitation systems; and complete formulation of antimicrobial delivery vehicle for prevention of dental disease. In FY07, will complete analysis of data to obtain algorithms for prediction of cardiovascular collapse and indicate the need to apply a LSI; will complete clinical validation of closed loop fluid infusion system; will evaluate neuroprotective drugs for reduction of morbidity following burn injury; and establish antimicrobial activity profiles in animals for prevention

FY 2004	FY 2005	FY 2006	FY 2007
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4084	4425	4570	5423
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February 2005

BUDGET ACTIVITY  
**3 - Advanced technology development**

PE NUMBER AND TITLE  
**0603002A - MEDICAL ADVANCED TECHNOLOGY**

PROJECT  
**840**

**Accomplishments/Planned Program (continued)**

Combat Casualty Bioinformatics and Simulation - including a far-forward-compatible system for creation and management of patient records and theater regulation of patient flow and development of casualty simulations and durable, realistic simulators for initial and reinforcement training of care providers. In FY04, in conjunction with Research Development and Engineering Command, matured a methodology to support combat medic training in a highly distributed environment, including treatment of patients exposed to chemical, biological, and nuclear weapons. In FY05, complete a prototype patient simulator with advances in materiel sciences, including realistic skin and physiologically accurate injuries, sensor technologies, miniaturization/packaging technology and ad hoc wireless networking. In FY06, will complete testing the system to assess training effectiveness for transition to the Army Medical Department Center and School. In FY07, will deliver a deployable, untethered, robust, self-correcting, self-assessing medical simulation training system for far-forward care providers.

FY 2004	FY 2005	FY 2006	FY 2007	
1590	919	1470	691	
<b>Totals</b>	<b>15479</b>	<b>12362</b>	<b>19502</b>	<b>22255</b>

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February 2005

**BUDGET ACTIVITY**  
**3 - Advanced technology development**

**PE NUMBER AND TITLE**  
**0603002A - MEDICAL ADVANCED TECHNOLOGY**

**PROJECT**  
**FH4**

COST (In Thousands)		FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
		Actual	Estimate						
FH4	FORCE HEALTH PROTECTION - ADV TECH DEV	0	0	1936	2114	2148	2190	2233	2277

**A. Mission Description and Budget Item Justification:** Force Health Protection Research seeks to enhance protection of Service members against health threats in military deployments both by increasing our understanding of military health issues through advanced technology research and by applying findings from a decade of research on the etiology (cause and origin of disease) and treatment of Gulf War Illnesses (GWI). This program is conducted in close coordination with the Department of Veterans Affairs. The program is divided into five thrust areas: (1) global health monitoring, (2) health behavior interventions, (3) health risk communication, (4) health risk assessment methods, and (5) medical materiel safety. This project contains no duplication with any 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 U.S. Army Research Institute of Environmental Medicine, Natick, MA; the Naval Health Research Center, San Diego, CA; and the U.S. Army Center for Environmental Health Research, Fort Detrick, MD.

<b>Accomplishments/Planned Program</b>	FY 2004	FY 2005	FY 2006	FY 2007
In FY06, will demonstrate the cross-linkage between physical activity, weight management and healthy lifestyle to assess research findings and linkages to symptoms identified in these activities to the condition described as "chronic multi-symptom illness."	0	0	1936	2114
In FY07, will determine the effectiveness of current and state-of-the-art programs for healthy lifestyles (tobacco cessation and preventing alcohol abuse) in the military environment to assess research findings linking these approaches to the condition described as chronic multi-symptom illness.				
<b>Totals</b>	0	0	1936	2114