ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2005

BUDGET ACTIVITY
2 - Applied Research

PE NUMBER AND TITLE
0602787A - MEDICAL 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	174622	183102	74694	74804	74821	72654	73480	74228
841	COMPUTER-ASST MINIMALLY INVASIVE SURGERY	1363	0	0	0	0	0	0	0
845	BONE DISEASE RESEARCH PROGRAM	0	958	0	0	0	0	0	0
863	BTLFLD SURGICAL REPLAC	2922	3835	0	0	0	0	0	0
865	CENTER FOR MILITARY BIOMATERIALS RESEARCH	1461	2397	0	0	0	0	0	0
866	CLINICAL TRIAL PLEZOELECTRIC DRY POWDER INHALATION	0	3835	0	0	0	0	0	0
867	DIAGNOSTICS IN TRAUMATIC BRAIN INJURY BLOOD BASED	975	2876	0	0	0	0	0	0
869	T-MED/ADVANCED TECHNOLOGY	3189	2992	2837	2960	3096	3139	3176	3208
870	DOD MED DEF AG INF DIS	13323	13769	14958	14781	15088	15373	15526	15659
873	HIV EXPLORATORY RSCH	10842	9532	10971	11313	11555	11424	11523	11608
874	CBT CASUALTY CARE TECH	8782	7613	15625	13599	11997	9141	9220	9287
878	HLTH HAZ MIL MATERIEL	11419	10779	12738	13753	14337	14546	14731	14900
879	MED FACT ENH SOLD EFF	8868	9736	9821	9940	10158	10270	10369	10454
953	DISASTER RELIEF & EMERGENCY MEDICAL SVC (DREAMS)	10713	10546	0	0	0	0	0	0
968	SYNCH BASED HI ENERGY RADIATION BEAM CANCER DETECT	22157	8148	0	0	0	0	0	0
96A	EMERGENCY HYPOTHERMIA	2239	0	0	0	0	0	0	0
96C	DIGITAL IMAGING AND CATHERIZATION EQUIPMENT	975	0	0	0	0	0	0	0
96E	HEMORRHAGE CONTROL DRESSING	2922	3356	0	0	0	0	0	0
96F	PORTABLE BIOCHIP ANALYSIS SYSTEM	0	958	0	0	0	0	0	0
96I	REMOTE ACOUSTIC HEMOSTASIS	3408	0	0	0	0	0	0	0
FH2	FORCE HEALTH PROTECTION - APPLIED RESEARCH	0	0	7744	8458	8590	8761	8935	9112

MA2	DIABETES PROJECT	6575	5752	0	0	0	0	0	0
MA3	MEDICAL AREA NETWORK FOR VIRTUAL TECHNOLOGY	5746	4889	0	0	0	0	0	0
MA5	CENTER FOR INTERNATIONAL REHABILITATION	3408	4793	0	0	0	0	0	0
MA6	DERMAL PHASE METER	1169	958	0	0	0	0	0	0
MA8	MONOCLONAL ANTIBODY BASED TECHNOLOGY	1461	0	0	0	0	0	0	0
NA7	ADVANCED SURGICAL NAVIGATION (CA)	1753	0	0	0	0	0	0	0
NA8	IMPROVING SOLDIER PERFORMANCE (CA)	2338	1727	0	0	0	0	0	0
NA9	BEHAVIORAL GENOMICS (CA)	1948	0	0	0	0	0	0	0
OA1	BIO-DEFENSE GENE KNOCKOUT TECHNOLOGY (CA)	2045	0	0	0	0	0	0	0
OA2	BIOMEDICAL ENG TECH AND ADV MATERIALS (CA)	975	0	0	0	0	0	0	0
OA3	CENTER FOR ADV SURGICAL & INTERVENTIONAL TECH (CA)	2045	958	0	0	0	0	0	0
OA4	CHRONIC MULTI-SYMPTOM ILLNESSES (CA)	4870	0	0	0	0	0	0	0
OA5	COMPUTATION PROTEOMICS (CA)	2922	2492	0	0	0	0	0	0
OA6	CONJUGATE VACCINES TO PREVENT SHIGELLOSIS (CA)	1363	0	0	0	0	0	0	0
OA7	ELGEN GENE DELIVERY TECHNOLOGY (CA)	975	958	0	0	0	0	0	0
OA8	ENHANCED RES IN TRAUMA PREVENTION/TREATMENT/REHAB	1461	1917	0	0	0	0	0	0
OA9	GENETIC ACUTE ENHANCED BIOWARFARE THERAPY PROG (CA	975	0	0	0	0	0	0	0
PA1	HEMOGLOBIN BLOOD OXYGEN CARRIER (CA)	975	0	0	0	0	0	0	0
PA2	LARGE-SCALE/POLYCLONAL/HUMAN ANTIBODY PRODUCTION	2922	0	0	0	0	0	0	0

PA4	WOUND HEALING PROJECT (CA)	3020	0	0	0	0	0	0	0
PA5	NANOFABRICATED BIOARTIFICIAL KIDNEY (CA)	2338	1869	0	0	0	0	0	0
PA6	NATIONAL TISSUE ENGINEERING RESEARCH (CA)	975	0	0	0	0	0	0	0
PA7	NON-INVASIVE MEDICAL SENSORS (CA)	1461	958	0	0	0	0	0	0
PA8	NOVEL GROWTH FACTOR DELIVERY TECHNOLOGY (CA)	975	0	0	0	0	0	0	0
PA9	PROSTHETIC DEVICE CLIN EVAL AT WRAIR AMPUTEE CTR	2435	0	0	0	0	0	0	0
RA1	SLEEP DEPRIVATION RESEARCH AT WRAMC (CA)	1461	3356	0	0	0	0	0	0
RA2	TARGETED NANOTHERAPEUTICS FOR CANCER (CA)	975	958	0	0	0	0	0	0
RA3	THERAPEUTIC VACCINES FOR BIOLOGICAL THREAT (CA)	975	0	0	0	0	0	0	0
RA4	TRANSPORTABLE PATHOGEN REDUCT AND BLOOD SAFETY SYS	1948	1917	0	0	0	0	0	0
RA5	USAMRIID ANTHRAX RESEARCH (CA)	2435	2156	0	0	0	0	0	0
RA6	VERSA HSDI (CA)	4140	4122	0	0	0	0	0	0
TA1	AUTO MEDICAL EMERGENCY INTRAVASCULAR ACCESS (CA)	0	958	0	0	0	0	0	0
TA2	ANTI-MICROBIAL COATINGS FOR MEDICAL DEVICES (CA)	0	1343	0	0	0	0	0	0
TA3	BIOACTIVE PRODUCTS PROGRAM FOR BREAST CANCER (CA)	0	958	0	0	0	0	0	0
TA4	HEALTH EFFECTS OF IONIZING RADIATION (CA)	0	958	0	0	0	0	0	0
TA5	CHRONIC WOUNDS (NON-HEALING) RESEARCH (CA)	0	958	0	0	0	0	0	0
TA6	COLLABORATIVE PROGRAM IN REHAB & ENGINEER RSH (CA)	0	958	0	0	0	0	0	0

TA7	COMBAT CASUALTY CARE FOR BATTLEFIELD WOUNDS (CA)	0	2685	0	0	0	0	0	0
TA8	COMPREHENSIVE BIOACTIVE PROD PRG FOR BREAST CANCER	0	958	0	0	0	0	0	0
TA9	COMPREHENSIVE REPRODUCTIVE SYS CARE PROGRAM (CA)	0	11408	0	0	0	0	0	0
UA1	GYNECOLOGICAL CANCER CENTER (CA)	0	2013	0	0	0	0	0	0
UA2	HIGH-SPEED MEMS ELECTROMAGNETIC CELL SORTER (CA)	0	1438	0	0	0	0	0	0
UA3	MATERNAL-FETAL HEALTH INFORMATICS & OUTREACH PRGM	0	958	0	0	0	0	0	0
UA4	INTEGRATIVE CARDIAC HEALTH PROGRAM (CA)	0	4889	0	0	0	0	0	0
UA5	NEUTRON THERAPY (CA)	0	863	0	0	0	0	0	0
UA6	PREDICTIVE TOOLS FOR PTSD (CA)	0	958	0	0	0	0	0	0
UA7	PREVENTIVE MEDICINE RESEARCH INSTITUTE (CA)	0	1438	0	0	0	0	0	0
UA8	PROTEIN HYDROGEL (CA)	0	958	0	0	0	0	0	0
UA9	MEDICAL SKILLS READINESS TRNG FOR RESERVISTS (CA)	0	1438	0	0	0	0	0	0
VA1	SHOCK TRAUMA RESEARCH (CA)	0	2013	0	0	0	0	0	0
VA2	SPINAL MUSCULAR ATROPHY RESEARCH PROGRAM (CA)	0	2156	0	0	0	0	0	0
VA3	VETERINARY MANPOWER DEVELOPMENT (CA)	0	288	0	0	0	0	0	0
X05	MOLECULAR GENETICS & MUSCULOSKELETAL RESEARCH(CA)	0	11398	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 and funds research consistent with the Medical, Survivability, and Future Warrior 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 medical research and development is to sustain medical technology to effectively protect and improve the survivability of U.S. forces in a variety of settings including, but not limited to: conventional/asymmetric battlefields, areas of low-intensity conflict, and military operations other than war.

This program element funds applied research in the following areas: Militarily-Relevant Infectious Diseases including HIV, Combat Casualty Care, and Military Operational Medicine that includes exposure to hazardous military materiels, medical factors to enhance soldier effectiveness, telemedicine, and force health protection.

Infectious Diseases: Focuses applied research on medical protection against naturally occurring diseases of military importance. Methods are identified and matured for infectious disease prevention and treatment including candidate vaccines, prophylactic intervention, therapeutic drugs, and control of disease-carrying insect vectors. HIV Exploratory Research focuses applied research on diagnostics, surveillance, epidemiology, and identification of candidate vaccines for prevention and treatment of HIV subtypes found outside the U.S., which are problematic in military deployments. Main efforts include preclinical development of candidate vaccines, improved diagnosis, and improved prognostic assessment and disease management.

Combat Casualty Care: Focuses applied research for the care of trauma and burns due to battlefield injuries. Drugs, biologics, and diagnostics for resuscitation and life support are identified and evaluated, as well as, trauma care systems for forward medic and surgeon use. It also includes Combat Dentistry research with a focus on prevention of cavities and dental disease and combat maxillofacial (face/neck) injuries on the battlefield.

Military Operational Medicine (MOM): Focuses on biomedical solutions that protect soldiers and enhance their performance in the face of multiple stressors in operational and training environments. Research examines methods such as soft body armor and biomonitors to protect soldiers from injuries resulting from exposure to hazardous environments and materiels. Prevention of health and performance degradation in military environments is another important objective of MOM research. This research examines 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. Additionally, 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.

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 Research Institute of Chemical Defense, Aberdeen Proving Ground, MD; U.S. Army Medical Research 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; U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL; and for infectious disease research, the Naval Medical Research Center, Silver Springs, MD.

B. Program Change Summary	FY 2005	FY 2006	FY 2007
Previous President's Budget (FY 2005)	60877	69782	67732
Current Budget (FY 2006/2007 PB)	183102	74694	74804
Total Adjustments	122225	4912	7072
Net of Program/Database Changes			
Congressional Program Reductions	-7465		
Congressional Rescissions	-143		
Congressional Increases	133850		
Reprogrammings			
SBIR/STTR Transfer	-4017		
Adjustments to Budget Years		4912	7072

Change Summary Explanation:
Funding - FY 2006/2007: Funds realigned from PE 0601105A to new project FH2 for proper execution of Force Health Protection Program in accordance with DoD Financial Management Regulation Budget Activity definitions (FY 06 +7744/FY 07 +8294).
Also funds were realigned to higher priority requirements (FY 06 -1055/FY 07 -280).

Forty-Seven FY05 Congressional adds totaling $133850 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	PE NUMBER AND TITLE	PROJECT
2 - Applied Research	**0602787A - MEDICAL TECHNOLOGY**	**869**

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
869	T-MED/ADVANCED TECHNOLOGY	3189	2992	2837	2960	3096	3139	3176	3208

A. Mission Description and Budget Item Justification: This project supports focused research for the soldier contributing to casualty avoidance, casualty detection, and evacuation and treatment of casualties through application of physiological status monitoring technologies (biophysical and biochemical sensors and fusion) as outlined in the Medical and Future Force Technology Areas. Research efforts focus on developing a wearable, integrated system to determine soldier physiological status. Work is performed in conjunction with the Natick Soldier Center. This includes developing the ability to quickly and accurately determine when a soldier is minimally impaired but still capable of functioning. Work will also focus on identification and initial development of parallel and supporting technologies and systems, including medical informatics, medical artificial intelligence, and data mining tools. Work is performed in coordination with Natick Soldier Center. 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; U.S. Army Research Institute of Environmental Medicine, Natick, MA; and the U.S. Army Institute of Surgical Research, Fort Sam Houston, TX.

Accomplishments/Planned Program	FY 2004	FY 2005	FY 2006	FY 2007
High Altitude Performance/Life Sign Monitoring - In FY04, determined that carbohydrate supplements ingested during physical activity in high altitude environments enhanced performance outcomes, enabling nonacclimatized soldiers rapidly deployed to high altitude environments to sustain optimal performance. An initial user-acceptable suite was selected to include Life Signs Detection and Ballistic Impact Detection systems with heat strain and sleep status monitoring capability to support key capabilities of Future Force Warrior (FFW)/Land Warrior Systems. In FY05, demonstrate ability to noninvasively monitor alertness in real-time operational settings, measure blood pressure, and incorporate this information into remote triage algorithm for FFW medic, complete human prospective trials of a fieldable acoustic collapsed lung detector; begin investigation of markers for the onset of cardiovascular collapse and algorithms to predict onset of shock. In FY06, will complete integration of the sensor suite and algorithms with the Personal Area Network and complete integration of the initial capability with FFW Advanced Technology Demonstration; conduct evaluation of relationships among variables that signal cardiovascular collapse and indicate a need to apply a Life Saving Intervention. In FY07, will complete analysis of data to refine algorithms for prediction of cardiovascular collapse.	3189	2992	2837	2960
Totals	3189	2992	2837	2960

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February 2005

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - Applied Research	**0602787A - MEDICAL TECHNOLOGY**	**870**

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
870 DOD MED DEF AG INF DIS	13323	13769	14958	14781	15088	15373	15526	15659

A. Mission Description and Budget Item Justification: This project researches and investigates medical countermeasures to naturally occurring infectious diseases, which pose a significant threat to the operational effectiveness of forces deployed outside the United States. Countermeasures will protect the force from infection and sustain operations by preventing hospitalizations and evacuations from the theater of operations. Of major importance to the military are the parasitic disease malaria, bacterial diseases responsible for diarrhea (i.e., caused by Shigella, enterotoxigenic Escherichia coli (ETEC), and Campylobacter), and viral diseases (e.g., dengue fever and hantavirus). Research also explores improved materiel to control arthropod (insects, ticks, etc.) disease vectors to reduce incidence of these diseases and addresses a variety of other threats to mobilizing forces, including meningitis, viral encephalitis, scrub typhus, and hemorrhagic fevers. Improved diagnostic capabilities are pursued to enable rapid battlefield identification and treatment or management of militarily important diseases for which there is no current method of protection. Goals include developing DNA (gene-based) vaccines; incorporating new technologies to enhance effectiveness, safety, and duration of vaccines; integrating cutting-edge genomic and proteomic (protein-based) technologies into vaccine and drug discovery; developing broad spectrum vaccines that can protect against multiple disease strains and drugs to prevent or treat malaria. 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.

Accomplishments/Planned Program	FY 2004	FY 2005	FY 2006	FY 2007
Malaria Vaccines - In FY04, produced malaria parasites for use in clinical challenge studies and test development; generated protein and virus-based vaccines against malaria; conducted preclinical safety and protection studies of these vaccines. In FY05, develop and assess additional/improved vaccine antigens and delivery systems (including recombinant proteins, adjuvants, nucleic acids, recombinant viruses, administration, schedule, and doses) that induce protective immune responses. Continue preclinical testing of DNA and protein vaccine candidates for inclusion into a multicomponent malaria vaccine. In FY06, will begin to down-select best vaccine delivery strategy and antigen selection for inclusion into a multicomponent vaccine. In FY07, will improve the current clinical efficacy of lead vaccine candidates by using improved antigen and adjuvant combinations, and assess new vaccine delivery methods for potential enhancement of best vaccine candidates.	2397	2830	2670	2700
Antidiarrheal Vaccines - In FY04, refined surrogate assays to measure protection by vaccines and develop better animal models for assessing efficacy of vaccines; conducted preclinical testing of candidate antidiarrheal vaccines to support Investigational New Drug (IND) applications to the U.S. Food and Drug Administration (FDA) established process for generating candidate ETEC vaccine proteins for preclinical testing. In FY05, conduct preclinical testing of most advanced candidate vaccines; establish an animal model for use in preclinical testing of ETEC vaccines. In FY06, will complete preclinical testing of selected candidate vaccines; assess more effective delivery methods such as biological adjuvant for vaccines against diarrheal pathogens; assess non-vaccine approaches to protect against diarrhea such as oral immunoglobulin (animal protein with known antibody activity) supplementation. In FY07, will assess a combined vaccine approach for a broad spectrum anti-diarrheal vaccine.	2425	3267	2391	1948
Insect Control - In FY04, performed final evaluation of selected repellent with human volunteers, compared effectiveness in human trials to other available repellents, to down-select to a highly effective new non-DEET repellent. In FY05, complete testing of a dengue vector control system. In FY06, will enhance traditional identification aids for mosquitoes of medical importance. In FY07, will develop field expedient vector-based pathogen detection kits and assays for use in the field.	960	687	725	1526

Accomplishments/Planned Program (continued)	FY 2004	FY 2005	FY 2006	FY 2007
Scrub Typhus Vaccine and Infectious Disease Diagnostics - In FY04, completed construction of a multistrain vaccine and tested for safety and protection in animal studies; identified infectious disease diagnostic components compatible for use with Joint Biological Agent Identification and Diagnosis System. In FY05, start preclinical testing of scrub typhus vaccine to justify FDA Phase 1 clinical trials of candidate vaccine; develop approaches to supplement infectious disease diagnostics. In FY06, will evaluate multistrain scrub typhus vaccine candidates in a heterologous (made up of tissue not normal to the part) challenge mouse model; complete initial development of a new diagnostic for dengue virus or other threat. In FY07, will evaluate selected vaccine candidates for safety and immunogenicity in preclinical studies; provide an additional diagnostic reagent (based on reaction it causes is used for analysis and synthesis) set for final development.	1347	1464	2293	2012
Vaccines against Dengue Fever, Meningitis and Hemorrhagic Fevers - In FY04, selected the most promising new dengue vaccines for clinical trials and improved as needed; and performed preclinical testing of a new component of a multistrain meningitis vaccine. In FY05, complete and improve construction of the second hantavirus vaccine component to provide complete protection against hemorrhagic fevers with renal syndrome. In FY06, will test new component for an improved meningitis vaccine; evaluate alternative methods (DNA, RNA, inactivated, designed mutant, vectored, replicon (replicating DNA), and/or new adjuvants (substance that enhances reaction of body)) for making second-generation dengue vaccines. In FY07, will conduct preclinical testing of improved dengue and group B meningitis vaccines.	2037	1848	3169	3227
Malaria Drug Candidates - In FY04, selected best drug candidates for preclinical and clinical studies using a systematic, streamlined approach for evaluation and optimization of new chemical entities. In FY05, continue to test new lead compounds identified in discovery via target-directed functional screens coupled with rational drug design technologies. In FY06, will continue to test best lead compound and identify new candidate drug classes coming from drug discovery program via target-directed functional screens coupled with rational drug design technologies. In FY07, will conduct in vivo testing of putative antimalarial drugs in a mouse malaria sporozoite challenge model; perform preclinical studies of new drug candidates; provide support for clinical trials of Artesunate, a promising new malaria drug.	4157	3673	3710	3368
Totals	13323	13769	14958	14781

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February 2005

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - Applied Research	**0602787A - MEDICAL TECHNOLOGY**	**873**

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
873	HIV EXPLORATORY RSCH	10842	9532	10971	11313	11555	11424	11523	11608

A. Mission Description and Budget Item Justification: This project supports the medical technology area of the Future Force by conducting applied research and development of improved diagnostics, surveillance, and epidemiology, and candidate vaccines for prevention and treatment of human immunodeficiency virus (HIV). This program is jointly managed through an Interagency Agreement between the U.S. Army Medical Research and Materiel Command and the National Institute of Allergy and Infectious Diseases. Main efforts include construction and preclinical development of candidate vaccines, including small animal and non-human primate studies, initial clinical development in humans, improved diagnosis of HIV infection, and improved prognostic assessment and disease management of HIV-infected individuals. This project contains no duplication with any effort within the Military Departments or other government organizations. Work is related to, and fully coordinated with work funded in PE 0603105. 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; and the Naval Medical Research Center, Silver Spring, MD and its overseas laboratories. Most work is conducted under a cooperative agreement with the Henry M. Jackson Foundation, Rockville, MD.

Accomplishments/Planned Program	FY 2004	FY 2005	FY 2006	FY 2007
In FY04, constructed additional candidate vaccines that induce broader anti-HIV immune responses against various HIV subtypes found outside the United States, which are problematic in military deployments; continued genetic analysis of HIV subtypes isolated in Africa for integration into vaccine candidates for this region; developed HIV vaccine study populations for future field trials in Kenya and Uganda; supported global surveillance of HIV-1 and informed the U.S. military of the HIV threat in areas of potential troop deployment; maintained U.S. Military Clinical Intervention Network operated through Military Medical Treatment Facilities to study the frequency and impact of HIV/AIDS (Acquired Immune Deficiency Syndrome) in/on military populations; identified cost-effective drugs and care strategies to control HIV infection and transmission in military populations. In FY05, perform preclinical testing of candidate vaccines; continue genetic analysis of HIV subtypes isolated in Africa for integration into vaccine candidates for this region; continue field trials site development in Kenya, Uganda, and prepare Cameroon site for field trials; maintain global surveillance network for HIV-1 infections; maintain U.S MCIN operated through Military Treatment Facilities to study the frequency and impact of HIV/AIDS in/on military populations. In FY06 and FY07 will continue: preclinical testing of candidate vaccines; genetic analysis of HIV subtypes isolated in Africa for integration into vaccine candidates for this region; continue field trials site development in Tanzania and other regions most appropriate for clinical trial; to maintain global surveillance network for HIV-1 infections. Will continue to maintain: U.S. MCIN operated to study the frequency and impact of HIV/AIDS in/on military populations; technical watch for new antiretroviral drugs.	10842	9532	10971	11313
Totals	10842	9532	10971	11313

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2 - Applied Research	**0602787A - MEDICAL TECHNOLOGY**	**874**

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
874	CBT CASUALTY CARE TECH	8782	7613	15625	13599	11997	9141	9220	9287

A. Mission Description and Budget Item Justification: This project investigates potential treatments for weapons-induced trauma and shock caused by severe blood loss on the battlefield. This project funds the core technology base to develop concepts, techniques, and materiel for the treatment and return-to-duty of warfighters wounded in combat and to support low-intensity combat as well as military operations other than war. The primary goal is to provide technologies that save lives far-forward and maintain critical care at all levels of the battlefield. Major efforts include: hemorrhage control, blood and resuscitative fluids; combat trauma therapies; far-forward medical systems; and combat casualty bioinformatics and simulation. Applied research in combat casualty care focuses on the evaluation of concept feasibility for drugs, biologics, and diagnostics for resuscitation and life support as well as designing trauma care systems for advanced monitoring and testing, emphasizing products for forward medic and surgeon use. Major efforts center on resuscitation and life support to include blood products; resuscitation fluids; drugs and devices to control severe bleeding; methods to minimize, repair, and prevent injury; diagnostic and predictive indicators for remote triage and computerized, autonomous patient care; and casualty data gathering and mining and development of training simulators. Selected technologies are integrated in to the Medical Mission Packages incrementally to provide comprehensive far forward treatment to meet Future Force requirements. Project also funds research to reduce evacuations due to dental disease and reduce the medical logistics footprint on the battlefield. 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.

Accomplishments/Planned Program	FY 2004	FY 2005	FY 2006	FY 2007
Hemorrhage Control, Blood, and Resuscitative Fluids - including materials and systems for minimizing the effects of traumatic blood loss, preserving blood and blood products, and trauma resuscitation. In FY04, conducted animal studies of candidate drugs for restoring clotting in casualties with abnormalities; conducted in vitro testing and scientific characterization of freeze-dried plasma; identified three promising complement activation inhibitors. In FY05: complete animal studies of drugs to evaluate their potential to restore clotting function in casualties with abnormalities and submit Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for the most promising candidate; conduct animal testing of freeze-dried plasma; complete the evaluation of clotting factor activity stability; select best method for rapid inactivation of blood-borne pathogens; complete studies of low-volume fluid resuscitation; identify new candidate additives for fluids to improve resuscitation. In FY06 will complete: animal studies and sample analyses in blood coagulation studies; determination of freeze-dried plasma production techniques; begin studies of post-transfusion survival; engage a corporate partner with a Good Manufacturing Practices compliant facility for manufacturing freeze-dried plasma; conclude comparative studies of next generation resuscitation fluids; test approved complement inhibitors in animals to determine their safety; refine model for assessing resuscitation requirements. In FY07 will: scale up production of freeze-dried plasma; complete stability studies, and submit IND application to the FDA; select best technology for pathogen inactivation; recommend best new fluid for resuscitation; and select the most promising compliment activation inhibitor and introduce into clinical trials.	3953	3046	7855	6339

Accomplishments/Planned Program (continued)	FY 2004	FY 2005	FY 2006	FY 2007
Combat Trauma Therapies - including discovery and development of drugs, biologicals, and medical procedures to minimize the immediate and long term effects from battlefield injuries. In FY04: conducted experiments on an antimicrobial wound-cleaning device that was at least as good as current therapies, and on lightweight materials and splints for fracture stabilization; characterized a highly innovative and novel experimental model of penetrating "ballistic-like" brain injury; evaluated candidate neuroprotective drugs in cell culture that increase survival in an animal model of brain injury; and completed studies demonstrating that recombinant Factor VIIa is neuroprotective when administered to rats prior to a non-penetrating injury. In FY05: down-select and conduct clinical testing of an advanced prototype wound protective barrier device and submit an Investigational Device Exemption application to the FDA; continue studies in animal models to determine the effectiveness of candidate drugs to mitigate brain injury after head trauma; and conduct neuroprotection drug studies in the penetrating head injury (PHI) model to identify a drug to improve survival and residual brain function in casualties with brain injury. In FY06 will: evaluate wound cleaning/rapid debridement (surgical removal of foreign matter and dead tissue from a wound) and tissue viability assessment devices in animal models and select best bone substitute; use the PHI model in further studies to evaluate the body's response mechanisms to a PHI. In FY07 will: establish antimicrobial activity profiles in animals; study results of varying wound cleaning times; complete guidelines for resuscitation and evacuation of head-injured patients; and evaluate neuroprotective drugs.	1328	1443	2125	3273

Accomplishments/Planned Program (continued)	FY 2004	FY 2005	FY 2006	FY 2007
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: conducted proof of concept of collapsed lung detector; completed down-selection of the Life Signs Detection System for the Warfighter Physiological Monitoring System (WPSM); successfully completed a Phase 2 animal toxicity study of a candidate chemical additive for Meals Ready To Eat (MREs) that kills dental disease organisms and has no inherent toxicity and incorporated newly developed surface activating agents to aid in penetrating oral biofilms; and began research efforts into formulation and application methodology of an anticavity/antiplaque food additive to prevent dental disease. In FY05: design algorithms and sensors for closed loop life support; fabricate prototype collapsed lung detector; complete multiple initial WPSM sensor suite algorithms; and establish efficacy of antimicrobial agents against pre-existing dental biofilm. In FY06 will: complete integrated design for closed loop system host platform; integrate initial sensor suite and algorithms into Personal Area Network (PAN); complete integration into the Future Force Warrior Advanced Technology Demonstration; continue conducting experiments to provide additional data for identification of markers of impending shock and development of algorithms; evaluate relationships among variables that signal cardiovascular collapse and indicate the need to apply a Life Saving Intervention (LSI); and complete anticaries (prevents cavities and dental decay) delivery method formulation. In FY07 will: complete analysis of data to obtain algorithms for prediction of cardiovascular collapse and indicate the need to apply a LSI; establish antimicrobial activity profiles against dental caries in animals.	2198	2510	5158	3222

Accomplishments/Planned Program (continued)	FY 2004	FY 2005	FY 2006	FY 2007
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: incorporated the WPSM data set into the system and augmented functionalities to include query of time-series data and user-customization of the visualization of the time-series data; initiated the development of algorithms to assess the quality of the low-frequency time-series data, such as heart rate; conducted an extensive fact-gathering effort with the Army Medical Department Center and School's Department of Combat Medic Training; continued to identify and measure tissue properties for vocal cord, liver, and spleen tissue; received recognition of the VIRGIL™ Chest Trauma Training System as 1 of 10 "Army's Greatest Inventions of the Year" for 2003. In FY05: design extraction tools and data analysis algorithms and extend graphical tools and user interfaces; mature 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. Complete algorithms that assess the quality of the low-frequency time-series data. In FY06 will: incorporate features to allow warehousing of data from additional studies and deliver a fully deployable system; complete tests to assess interoperability. In FY07 will mature a prototype self-correcting medical simulation training system for far-forward providers.	1303	614	487	765
Totals	8782	7613	15625	13599

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2005

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - Applied Research	**0602787A - MEDICAL TECHNOLOGY**	**878**

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
878	HLTH HAZ MIL MATERIEL	11419	10779	12738	13753	14337	14546	14731	14900

A. Mission Description and Budget Item Justification: This project supports the Medical and Survivability technology areas of the Future Force with focused research for the soldier on protection from health hazards associated with materiel and operational environments. Emphasis is on identification of health hazards inherent to the engineering design and operational use of equipment, systems, and material used in Army combat operations and training. Major efforts include: laser protection; injury protection; soft body armor and evironmental extreme protection; and biomonitor system/dehydration research. Specific hazards include: repeated impact/jolt in combat vehicles and aircraft; blast overpressure and impulse noise generated by weapons systems; toxic chemical hazards associated with deployment into environments contaminated with industrial and agricultural chemicals; nonionizing radiation-directed energy sources (laser); and environmental stressors (e.g., heat, cold, and terrestrial altitude). Specific research tasks include: characterizing the extent of exposure to potential hazards; delineating exposure thresholds for illness or injury; identifying exposure thresholds for performance degradation; establishing biomedical databases to support protection criteria; and developing and validating models for hazard assessment, injury prediction, and health and performance 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 Walter Reed Army Institute of Research, Silver Spring, MD; U.S. Army Research Institute of Environmental Medicine, Natick, MA; the United States Army Center for Environmental Health Research, Fort Detrick, MD; and the U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL.

Accomplishments/Planned Program	FY 2004	FY 2005	FY 2006	FY 2007
Laser Protection Research - In FY04, transitioned genomic/proteomic (study of protein expression and function)-derived laser eye injury treatments through a non-human primate model and characterized protective efficacy of a frequency agile particle cell switch for military sights Results support use of non-linear particle cell switches in military optics. Evaluated emerging genomic and proteomic derived treatment strategies to identify effective treatments. In FY05:demonstrate advanced electrodiagnosis and advanced retinal imaging to assess the efficacy of treatments for laser induced injury; complete the State- of-the-Art Report on the Biomedical Implications of Military Laser Exposure. In FY06 will transition triage, treatment and protection strategies based upon the classification of the laser-induced retinal injury. In FY07 will conduct advanced neuroprotection studies for the prevention of retinal and brain cell injury.	3654	3685	3452	3653
Injury Protection (tactical vehicles, face/eye) - In FY04, provided validated repeated jolt guidelines and proposed standards for safe operations of tactical ground vehicles for use in the Health Hazard Assessment program. These guidelines and standards are used in weapon system development programs to assess the ride quality of tactical ground vehicles and identify risk of injury during normal vehicle operations. Provided performance standards for effective military restraint systems to guide vehicle developers to safer designs. Establish minimum performance levels of occupant restraint systems for use by vehicle developers. In FY05, conduct epidemiological review of blunt and penetrating face and eye injury. In FY06 will develop face and eye computational models and injury dose-response models. In FY07 will validate computational and physical models of the face and eye and propose injury-based protection criteria.	1303	794	2772	3247

Accomplishments/Planned Program (continued)	FY 2004	FY 2005	FY 2006	FY 2007
Soft Body Armor and Environmental Extreme Protection - In FY04: developed and tested soft body armor (SBA) impactor; completed animal tests with SBA impactor; completed porcine (derived from swine) and human finite element models (FEMs); developed anthropomorphic (i.e. human form) test module; and characterized forces behind hard body armor (HBA), resulting in a validated scientific method for predicting blunt trauma injuries behind body armor. In FY05: conduct animal studies with HBA impactor; use FEM to scale animal injury model to human injury model; and develop body armor blunt trauma injury prediction software. In FY06 will: validate anthropomorphic test module with animal test data and transition valid body armor testing method with human injury prediction software to the Research, Development and Engineering Command/Natick Soldier Center; conduct small animal cognitive performance tests, integrate results, and release interim Toxic Gas Assessment Software - Performance Evaluator results to the Center for Health Promotion and Preventive Medicine. In FY07 will conduct large animal physical performance tests and validate the Toxic Gas Assessment Software - Performance Evaluator against large animal physical performance data.	3605	3337	3300	3506
Biomonitor System/Dehydration Research - In FY04, completed initial technology assessment for the environmental sentinel biomonitor system, which identifies threats to drinking water quality. Through the Integrated Product Team process, reduced the number of candidate toxicity sensor technologies for the environmental sentinel biomonitor system from 38 to 13. In FY05, evaluate and select biomonitor components for the environmental sentinel biomonitor for rapid identification of acute toxic hazards in water. In FY06 will: evaluate and select environmental sentinel biomonitor components; determine dehydration consequences for cold and high mountain missions. In FY07 will: complete environmental sentinel biomonitor platform and expert system development; develop models to predict water needs for broad spectrum of modern missions in environmental extremes.	2857	2963	3214	3347
Totals	11419	10779	12738	13753

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2005

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - Applied Research	**0602787A - MEDICAL TECHNOLOGY**	**879**

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
879	MED FACT ENH SOLD EFF	8868	9736	9821	9940	10158	10270	10369	10454

A. Mission Description and Budget Item Justification: This project supports the Medical and Survivability technology areas of the Future Force with research for the soldier focused on preventing health and performance degradation in the military environment. Emphasis is on identification of baseline physiological performance and assessment of degradations produced by operational stressors. This database and collection of rules and algorithms for performance degradation in multistressor environments form the basis for the development of behavioral, training, pharmacological, and nutritional interventions to prevent decrements and sustain soldier performance. Key stressors include: psychological stress from isolation, new operational roles, and frequent deployments; inadequate restorative sleep; prolonged physical effort and inadequate hydration in extreme environments; desynchronization of biological rhythms during deployments across multiple time zones and night operations; and thermal and altitude stress. 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; U.S. Army Research Institute of Environmental Medicine, Natick, MA; and the U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL.

Accomplishments/Planned Program	FY 2004	FY 2005	FY 2006	FY 2007
Nutritional and High Altitude Research - In FY04, conducted heat evaluations on individual performance using existing operational and functional models of heat stress, resulting in a capability to predict variability in these performance components for individual outcomes based on environmental and operational variables. Completed a nutritional assessment of the effects of varied protein and energy intake levels on Warfighter diet. Results demonstrated that neither protein nor energy intake levels precluded a loss of body mass or lean mass in soldiers during extended field operations. In FY05, identify performance enhancing nutritional supplements for incorporation into altitude rations. In FY06 will develop pre-deployment doctrine to time compress altitude acclimatization. In FY07 will develop prediction models of altitude acclimatization, illness incidence, and work performance.	2215	2364	2377	2407
Fatigue/Sleep Research - In FY04, determined and modeled recovery rates following acute sleep deprivation vs. chronic sleep restriction, facilitating specification and prediction of the extent to which alertness and performance capacity vary across differing levels of sleep loss. In FY05, determine and model the effects of escalating doses of fatigue countermeasures. In FY06 will produce in the laboratory an initial version of the Fatigue Intervention Recovery Model (FIRM) that predicts recovery, variability, and countermeasures effects. In FY07 will conduct field studies to validate the FIRM predictions for militarily relevant performance.	1641	1984	2015	2039
Mental Health Research - In FY04, conducted a number of studies that identified factors that predict high rates of mental disorders and their association with readiness, particularly attrition. These findings have contributed to several major programs to reduce the burden of mental health problems associated with deployment, including the Army Deployment Cycle Support Program and the medical screening evaluation. In FY05, propose effective methods for psychological health screening in deployed troops. In FY06 will field test strategies such as psychological debriefing (e.g., following traumatic events) to reduce psychiatric illness in soldiers. In FY07 will develop criteria for identifying training and operational environments where soldiers are most susceptible to psychiatric illness.	2861	3359	3394	3435

Accomplishments/Planned Program (continued)	FY 2004	FY 2005	FY 2006	FY 2007
Vision and Auditory Research - In FY04, conducted study to determine impact of refractive surgery (photo refractive keratectomy (i.e., excision of a portion of the cornea) and laser insitu keratomileusis) on vision and flight performance and conducted study of visual detection model for displays and complex targets. Findings from refractive surgery study supported new Army Surgeon General policy for refractive surgery for Army aviators. The validation of the visual detection model was the final stage in developing a first-order model of the observer's visual and decision-making processes in target detection tasks. In FY05, define visual performance and image interpretation measurements for advanced displays, sensors, and optical materials. In FY06 will summarize the ability of hearing-impaired soldiers to use virtual auditory displays for speech and non-speech signals, and produce external peer reviewed, medically based auditory display guidelines for Army warfighters regardless of hearing profile. In FY07 will model warfighter visual perception, physiology, and performance for various monocular, binocular, and biocular display devices and optical media.	2151	2029	2035	2059
Totals	8868	9736	9821	9940

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2005

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - Applied Research	**0602787A - MEDICAL TECHNOLOGY**	**FH2**

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
FH2	FORCE HEALTH PROTECTION - APPLIED RESEARCH	0	0	7744	8458	8590	8761	8935	9112

A. Mission Description and Budget Item Justification: Force Health Protection (FHP) Research seeks to enhance protection of Service members against health threats in military deployments both by increasing our understanding of military health issues through applied 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). FHP research is conducted in close coordination with the Department of Veterans Affairs. It includes 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.

Accomplishments/Planned Program	FY 2004	FY 2005	FY 2006	FY 2007
Health Research - In FY06 will demonstrate preliminary associations between military service and specific illness and injury consequences. In FY07 will conduct major data collection through recruitment of new cohort of 20,000 Service members. The primary objective for this study is to compare change in health status between deployed and non-deployed personnel and the adjusted incidence rates of chronic disease between cohorts. Secondary objectives include comparing the adjusted change in health between the cohorts based on self-assessed physical and mental well being, mental health diagnoses from the Patient Health Questionnaire diagnostic assessment, and the post-traumatic stress disorder assessment. This study will serve as a foundation upon which other routinely captured medical and deployment data may be added to answer future questions regarding the health risks of military deployment, military occupations, and general military service.	0	0	3200	3430
Health Behavior/Weight Control - In FY06 will evaluate the effectiveness of health behaviors training program (sexually transmitted diseases, unintended pregnancy, and sexual violence prevention), comparing co-ed training in Army initial entry training (IET), with single gender training in Marine IET. In FY07 will determine the benefit of the use of new anti-obesity agents for treatment of over weight soldiers lacking any associated co-morbidities (related sickness), as a preventive measure for later morbid conditions (e.g., hypertension).	0	0	2020	2424
Weight Control/Physical Training – In FY06 will determine the effectiveness of a comprehensive weight management program for over weight soldiers. In FY07 will demonstrate the effectiveness of physical training injury reduction guidance.	0	0	2524	2604
Totals	0	0	7744	8458